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Mary Madison)
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)
)
Plaintiff(s),)
)
v.)
Creative Werks, LLC)
)
Steve Schroeder)
)
Defendant(s).)

Case Number: 1:23-cv-16476
Judge Elaine E. Bucklo
Magistrate Judge Beth W. Jantz
RANDOM
Cat. 2

FILED
DEC 04 2023
THOMAS G. BRUTON
CLERK, U.S. DISTRICT COURT

COMPLAINT OF EMPLOYMENT DISCRIMINATION

1. This is an action for employment discrimination.
2. The plaintiff is Mary Madison of the
county of Cook in the state of Illinois.
Creative Werks is a corporation organized in Delaware
3. The defendant is and Steve Schroeder, whose
street address is 1460 Brummel,
(city) Elk Grove Village (county) Cook (state) Illinois (ZIP) 60007
(Defendant's telephone number) (630) -860-2222
4. The plaintiff sought employment or was employed by the defendant at (street address)
1460 Brummel (city) Elk Grove Village
(county) Cook (state) Illinois (ZIP code) 60007

[If you need additional space for ANY section, please attach an additional sheet and reference that section.]

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5. The plaintiff [*check one box*]

- (a) ☐ was denied employment by the defendant.
- (b) ☐ was hired and is still employed by the defendant.
- (c) ☒ was employed but is no longer employed by the defendant.

6. The defendant discriminated against the plaintiff on or about, or beginning on or about, (month) October, (day) 26, (year) 2022.

7.1 (*Choose paragraph 7.1 or 7.2, do not complete both.*)

- (a) The defendant is not a federal governmental agency, and the plaintiff [*check one box*] ☒ has ☐ has not filed a charge or charges against the defendant

asserting the acts of discrimination indicated in this complaint with any of the following government agencies:

- (i) ☒ the United States Equal Employment Opportunity Commission, on or about (month) August (day) 21 (year) 2023. **See Attached Exhibit 1**
- (ii) ☒ the Illinois Department of Human Rights, on or about **Currently under investigation see attached Exhibit 2** (month) _____ (day) _____ (year) _____.

- (b) If charges *were* filed with an agency indicated above, a copy of the charge is attached. ☒ Yes, ☐ No, **but plaintiff will file a copy of the charge within 14 days.**

It is the policy of both the Equal Employment Opportunity Commission and the Illinois Department of Human Rights to cross-file with the other agency all charges received. The plaintiff has no reason to believe that this policy was not followed in this case.

7.2 The defendant is a federal governmental agency, and

- (a) the plaintiff previously filed a Complaint of Employment Discrimination with the

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defendant asserting the acts of discrimination indicated in this court complaint.

☐ Yes (month)_____ (day)_____ (year) _____

☐ No, did not file Complaint of Employment Discrimination

(b) The plaintiff received a Final Agency Decision on (month)_____
(day) _____ (year) _____.

(c) Attached is a copy of the

(i) Complaint of Employment Discrimination,

☐ Yes ☐ No, but a copy will be filed within 14 days.

(ii) Final Agency Decision

☐ Yes ☐ NO, but a copy will be filed within 14 days.

8. (Complete paragraph 8 only if defendant is not a federal governmental agency.)

(a) ☐ the United States Equal Employment Opportunity Commission has not
issued a *Notice of Right to Sue*.

(b) ☒ the United States Equal Employment Opportunity Commission has issued
a *Notice of Right to Sue*, which was received by the plaintiff on
(month) September (day) 5 (year) 2023 a copy of which
Notice is attached to this complaint. **See Attached Exhibit 3**

9. The defendant discriminated against the plaintiff because of the plaintiff's [**check only
those that apply**]:

(a) ☒ Age (Age Discrimination Employment Act).

(b) ☐ Color (Title VII of the Civil Rights Act of 1964 and 42 U.S.C. §1981).

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- (c) ☐ Disability (Americans with Disabilities Act or Rehabilitation Act)
 - (d) ☐ National Origin (Title VII of the Civil Rights Act of 1964 and 42 U.S.C. §1981).
 - (e) ☒ Race (Title VII of the Civil Rights Act of 1964 and 42 U.S.C. §1981).
 - (f) ☐ Religion (Title VII of the Civil Rights Act of 1964)
 - (g) ☒ Sex (Title VII of the Civil Rights Act of 1964)
10. If the defendant is a state, county, municipal (city, town or village) or other local governmental agency, plaintiff further alleges discrimination on the basis of race, color, or national origin (42 U.S.C. § 1983).
11. Jurisdiction over the statutory violation alleged is conferred as follows: for Title VII claims by 28 U.S.C. §1331, 28 U.S.C. §1343(a)(3), and 42 U.S.C. §2000e-5(f)(3); for 42 U.S.C. §1981 and §1983 by 42 U.S.C. §1988; for the A.D.E.A. by 42 U.S.C. §12117; for the Rehabilitation Act, 29 U.S.C. § 791. **42 U.S.C. § 2000e et Seq., and 42 U.S.C. §1985(3)**
12. The defendant [*check only those that apply*]
- (a) ☐ failed to hire the plaintiff.
 - (b) ☒ terminated the plaintiff's employment.
 - (c) ☐ failed to promote the plaintiff.
 - (d) ☐ failed to reasonably accommodate the plaintiff's religion.
 - (e) ☐ failed to reasonably accommodate the plaintiff's disabilities.
 - (f) ☒ failed to stop harassment;
 - (g) ☒ retaliated against the plaintiff because the plaintiff did something to assert rights protected by the laws identified in paragraphs 9 and 10 above;
 - (h) ☒ other (specify): See Attached #12(h)

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[If you need additional space for ANY section, please attach an additional sheet and reference that section.]

13. The facts supporting the plaintiff's claim of discrimination are as follows:

See attached #13

14. **[AGE DISCRIMINATION ONLY]** Defendant knowingly, intentionally, and willfully discriminated against the plaintiff.

15. The plaintiff demands that the case be tried by a jury. ☒ Yes ☐ No

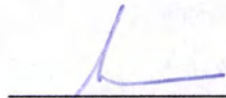
16. THEREFORE, the plaintiff asks that the court grant the following relief to the plaintiff **[check only those that apply]**

- (a) ☐ Direct the defendant to hire the plaintiff.
- (b) ☒ Direct the defendant to re-employ the plaintiff.
- (c) ☐ Direct the defendant to promote the plaintiff.
- (d) ☐ Direct the defendant to reasonably accommodate the plaintiff's religion.
- (e) ☐ Direct the defendant to reasonably accommodate the plaintiff's disabilities.
- (f) ☒ Direct the defendant to (specify): See Attached # 16(f)

[If you need additional space for ANY section, please attach an additional sheet and reference that section.]

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- (g) ☒ If available, grant the plaintiff appropriate injunctive relief, lost wages, liquidated/double damages, front pay, compensatory damages, punitive damages, prejudgment interest, post-judgment interest, and costs, including reasonable attorney fees and expert witness fees.
- (h) ☒ Grant such other relief as the Court may find appropriate.



(Plaintiff's signature)

Mary Madison

(Plaintiff's name)

9758 S. Charles

(Plaintiff's street address)

(City) Chicago (State) IL (ZIP) 60643

(Plaintiff's telephone number) (773) - 297-9569

Date: December 4, 2023

[If you need additional space for ANY section, please attach an additional sheet and reference that section.]

12. 12(h) supplemental Attachment

VIOLATION OF TITLE VII (DISPARATE TREATMENT)

Defendants conduct as alleged at length herein constitutes discrimination based on race in violation of Title VII. The stated reasons for the Defendant's conduct were not the true reasons, but instead were pretext to hide the Defendant'(s) discriminatory animus.

As a direct and proximate result of the Defendants unlawful conduct in violation of Title VII, Madison has suffered and continues to suffer monetary and or/economic damages, including but not limited to, loss of past and future income, compensation and benefits for which she is entitled to an award of monetary damages and other relief.

As a direct and proximate result of the Defendants' unlawful conduct in violation of Title VII, Madison has suffered and continues to suffer severe mental anguish and emotional distress, including but not limited to, depression, humiliation, embarrassment, stress and anxiety, loss of self-esteem and self-confidence, and emotional pain and suffering for which she is entitled to an award of monetary damages and other relief.

As a direct and proximate result of the Defendants' conduct in violation of Title VII, Madison has suffered damage or injury to her reputation which diminishes her future earning capacity and Madison cannot be made whole without compensation for the lost earnings she would have received absent the Defendants' unlawful discrimination.

12. 12(h) supplemental Attachment

Defendants unlawful conduct constitutes a willful and wanton violation of Title VII, was outrageous and malicious, was intended to injure Madison, and was done with conscious disregard of Madison's civil rights, entitling her to an award of punitive damages.

VIOLATION OF SECTION 1981 (DISPARATE TREATMENT)

Defendants have violated Section 1981 by subjecting Madison to disparate treatment on the basis of her race and sex.

As a direct and proximate result of the Defendants unlawful conduct in violation of Section 1981, Madison has suffered and continues to suffer monetary and or/economic damages, including but not limited to, loss of past and future income, compensation and benefits for which she is entitled to an award of monetary damages and other relief.

As a direct and proximate result of the Defendants' unlawful conduct in violation of Section 1981, Madison has suffered and continues to suffer severe mental anguish and emotional distress, including but not limited to, depression, humiliation, embarrassment, stress and anxiety, loss of self-esteem and self-confidence, and emotional pain and suffering for which she is entitled to an award of monetary damages and other relief.

As a direct and proximate result of the Defendants' conduct in violation of Section 1981, Madison has suffered damage or injury to her reputation which diminishes her future earning capacity and Madison cannot be made whole without compensation for the lost earnings she would have received absent the Defendants' unlawful discrimination.

12. 12(h) supplemental Attachment

Defendants unlawful conduct constitutes a willful and wanton violation of Section 1981, was outrageous and malicious, was intended to injure Madison, and was done with conscious disregard of Madison's civil rights, entitling her to an award of punitive damages.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

1. Madison an African American, female, that began working at Creative Werks on September 27, 2022, and at the relevant time was the only African American, female manager at the corporate office.
2. Madison's responsibilities entailed compliance with the Food Safety Modernization Act "hereinafter referred to as FSMA" and other regulatory schemes such as the Bioterrorism Act of 2002 (Food Defense) in addition to being a liaison between customers and the company regarding compliance quality, regulatory and customer requirements (See Exhibit 4 FDA report pg. 8).
3. Madison at all relevant times met Defendant's legitimate expectations relative to her role and responsibilities as the Quality Regulatory Manager.
4. At all relevant times, Madison possessed the skills, education, experience, and qualifications necessary to work in her employment position and adequately and completely performed all of the functions, duties, and responsibilities of her employment with Defendant Creative Werks.
5. At all times, Steve Schroeder, ("Schroeder"), a White, male, held the position of Founder and President. Mr. Schroeder was in a position of authority to undertake tangible employment decisions and/or control the terms and conditions of Madison's employment with Defendant Creative Werks.
6. At all relevant times, Schroeder, acting on behalf of himself and his alter ego Creative Werks directed and approved all operational activities, including but not limited to hiring, pay, scheduling, performance management, workflow, and the like.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

7. At all relevant times, Erich Zicher, ("Zicher"), a White, male, coordinated regulatory, compliance, and quality activities relative to Creative Werks' operations, including but not limited to hiring, scheduling, workflow, investigations, safety, food defense, and safety plans, as well as, internal, external, federal, state and local compliance audits relative to the Food Drug and Cosmetic Act and other relevant statutes and the like.
8. Madison was hired for her expertise, as the Quality Regulatory Manager. Madison was to manage quality and regulatory issues internally and externally, with customers such as: Nestlé, Mondelez, General Mills, Hersey, Ghirardelli, Mars, Ferrara and Ferrero Candy, Tate's, and other snack food and confections companies, as well as, other companies such as Wilton Brands, Blue Diamond Growers among others; in addition to other relevant third (3rd) party stakeholders.
9. The FDA inspector initially visited the site on or about September 28, 2022¹, in response to a consumer complaint from October 2021. Present at the visit were Mr. Erich Zicher, who presented himself as the person in charge, Ms. Angela Knabe, Anupam Sharma and Madison. While waiting for the FDA Inspector Mr. Zicher began expressing his wanton disdain for the competency or the lack thereof for the FDA inspector, who turned out to be African American female.
10. Mr. Zicher's made continued disparaging remarks in a vile, animus, contemptuous and derogatory manner about the FDA Inspector and in particular her competency; remarking that she was incompetent, stupid and even at some point stating that her requisite knowledge was akin to that of an IRS agent. ZICHER further remarked with great hostility and disdain that in the FDA's previous inspection at Brummel, the

¹ There had been a previous consumer complaint in May/June 2021, regarding a Cheetos (Pepsi product).

13. The facts supporting the plaintiff's claim of discrimination are as follows:

Elk Grove Facility, the inspector's report made him look stupid and incompetent as if he did not know anything. Mr. Zicher spent a considerable amount of time ad nauseam maligning and denigrating the inspector.

11. Madison did not ever hear Mr. Zicher speak about anyone else in such a vehemently vile and animus manner as he did regarding the FDA Inspector, even when he talked about Donna Bjurlin from Nestlé Corporate Quality², a non-African-American female. He would refer to her requests as being "picky."

12. The FDA Inspector issued a notice of inspection--FDA form 482 to Defendant Zicher and began conducting the investigation relative to the Pepsi Cheetos complaint filed in October 2021 with the FDA.

13. Later that evening, Defendant Zicher instructed Madison not to produce or provide any requested documents to the FDA Inspector. Defendant Zicher stated that he was taught not to produce/provide documents to the inspectors and if they had to be produced only produce them electronically.

14. On or about September 29, 2022, the FDA inspector returned to the facility and had follow up questions for the team, which included responses to the Pepsi Cheetos complaint, and requests for additional documentation. Defendant Zicher was combative and non-compliant redirecting conversations to a consumer complaint that occurred May/June 2021, at that point, the inspector indicated that she wanted to tour the facility.

² Donna Bjurlin from Nestlé Corporate Quality held a longstanding biweekly meeting to address the outstanding audit deficiencies.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

15. Defendant Zicher stated that if Madison was accompanying them on the facility tour Madison's jewelry needed to be removed. He also indicated to Madison that she had a dress on.³
16. Ms. Knabe intervened and stated that Madison was all right to go, indicating that the company policy stated that one's extremities were to be covered. There was no exposed flesh; Madison's arms and legs were fully covered.
17. To minimize the discussion, Madison informed Defendant Zicher that she had pants in the car and that she would change.
18. Madison was unable to remove one of her screwed-in stud earrings. Per the FDA, jewelry is permissible, if secured.
19. Further the rule is geared towards those that come in direct contact with food, food-contact surfaces, and food-packaging materials (See 21 CFR Subpart B § 117.10 (b)(4)). For the purposes of this tour, Madison would not be in violation of the regulations. Moreover, additionally, hair restraints were also used that covered the ears and caught/restrained any particulate from being introduced into the manufacturing facility.
20. Madison did not pose any safety risk, as Madison was not going to be working on a line or coming into direct contact with any product, surface or packaging material. Thus, it would have been highly unlikely or improbable that any contamination would have occurred.
21. Defendant Zicher now asserts that the embellishments from Madison's prescription eyeglasses would pose a risk.

³ It was Plaintiff's first day at work. She was not aware that she would be making tours of the facility. She was fully aware of dress protocol for the purposes of making tours. The aforementioned was an unexpected event.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

22. Madison contends that any embellishments from Madison's prescription eyeglasses would not have posed a risk for the same reasons.⁴ Additionally, goggles could have been used to restrain any particulate from being introduced into the manufacturing facility.
23. Defendant Zicher asserts that Plaintiff had on nail polish. That assertion was patently false since Plaintiff Madison does not wear fingernail polish.
24. Further, Madison contends that her presence during the inspection was not essential, as Madison had just started and had not ever been to the facility before. Madison had no knowledge about the facility and its operation. Additionally, the person that Madison was replacing, Ms. Knabe did not accompany them either nor was she invited or required to go on the tour.
25. On Friday, September 30, 2022, as a follow-up and debriefing of the FDA visit, Mr. Zicher solicited input from Madison, Ms. Knabe and others on how to couch the FDA visit to craft his response and inform other clients of the FDA visit.
26. Also, about midmorning on September 30, 2022, Madison had a brief conversation with Mr. Schroeder at the espresso machine, where in particular Mr. Schroeder asked about the FDA investigation regarding Pepsi. Mr. Schroeder instructed Madison to ask Mr. Zicher to provide her with the questions that Mr. Schroeder had posed to Mr. Zicher regarding the FDA investigation and visit. Madison also agreed to share her initial analysis of the requests and observations made by the FDA Inspector. Mr. Schroeder stated that he "wanted to change the culture to be more transparent." He also stated "he hoped that Madison could be of help to the company."

⁴ Further, even knowing that an inspection was going to take place, there is nothing that could have been done to replace Madison's eyeglasses on such short notice.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

27. On September 30, 2022, as promised Madison shared the initial analysis of the September 28-29, 2022 FDA investigation and visit.
28. During the relevant time, Madison had no idea that a number of documents requested did not exist. Nor did Madison understand that the documents that did exist did not meet the requirements of FSMA, in particular 21 CFR 117, and the food defense under the Bioterrorism Act of 2002.
29. In attempting to remediate outstanding customer audit findings from July of 2022, from the Nestlé audit, Madison discovered that the food safety plans were either inadequate or did not exist in contravention of 21 CFR 117 and other food defense requirements under the Bioterrorism Act of 2002. Additionally, it was also discovered that Creative Works had repeated non-conforming audit findings that still had not been mitigated or remediated since the previous audit in 2021.
30. Madison communicated to Mr. Zicher these deficiencies and the non-compliances that underscored the audit deficiencies. Madison was told by Mr. Zicher on several occasions that Donna Bjurlin, from Nestlé, was being picky and that he was not inclined to make any changes.
31. Madison was also instructed by Mr. Zicher not to reference the regulations and standards when corresponding with Donna on behalf of Nestlé.
32. On October 3, 2022, Madison met Mr. Zicher at yet another Creative Werks facility in Bensenville to meet with a potential new customer Medfast.
33. While waiting for the potential clients, Mr. Zicher and Madison discussed the FDA audit/inspection. The discussion entailed the consumer complaint. It also entailed how Creative Werks seemed to be aware of the non-conforming/adulterated product that

13. The facts supporting the plaintiff's claim of discrimination are as follows:

had entered into the stream of commerce and that Creative Werks had not taken any remediation steps to prevent this from occurring. Madison shared with him that a good starting point was to understand what standards needed to comply with based upon the business operations.

34. Madison also shared with Mr. Zicher that Mr. Schroeder wanted him to share with her the questions that Mr. Schroeder had sent to him regarding the FDA visit on September 28-29, 2022.

35. Mr. Zicher indicated that Madison did not understand the culture there and that he would not be providing her with the information Mr. Schroeder asked to be shared with Madison. Zicher further stated that he and Ron Sammeth decided what Mr. Schroeder should know.

36. Among Madison's other responsibilities of attending meetings with customers and potential customers and conducting audits, she continued to conduct root cause analysis and other risk analysis relative to these and other outstanding customer and regulatory compliance issues that had not been remedied and due and owing since 2021.

37. Over the next few weeks, Madison sought information necessary to remediate outstanding issues but was instructed by Mr. Zicher to either provide false and/or misleading information to customers, or instructed to not comply, or provided with inadequate information to perform the job properly.

For example:

- I. Nestlé
- II. Wilton Brand
- III. Blue Diamond Growers

13. The facts supporting the plaintiff's claim of discrimination are as follows:

38. On October 4, 2022, Madison was told by Mr. Zicher not to worry about the deficiencies because in his experience “no one reads the documents” and to “use whatever documents that were there.”

39. Mr. Zicher instructed Madison to provide false, inaccurate and misleading information to clients after Madison specifically pointed out deficiencies in the documentation.

40. On October 6, 2022, the auditor, from Blue Diamond Growers, herein after “BDG,” Keira Kaur Dhillon came to perform the audit. The introductions began; Ms. Dhillon went first indicating that one of her previous employers was Kraft Foods. Madison went next and Mr. Zicher went last. Mr. Zicher led by stating to Ms. Dhillon that they had something in common because they both had worked at Kraft. She in turn asked him who was the CEO when he worked there? Mr. Zicher did not and could not answer her question--The room was filled with silence.

41. To deflect the awkward situation, Mr. Zicher made a mockery of Madison to Ms. Dhillon relative to all the tabs open on Madison's computer regarding the documents requested by BGD for review during the audit.

42. Madison responded to the effect that since they were kind enough to send over a comprehensive list of what they wanted to review during the audit and in the interest of everyone's time, it seemed prudent to be prepared and not to have to search for documents.

43. The auditor remarked that the audit exhibited readiness because of the readily available documents.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

44. Unfortunately, there was an issue identified by the auditor in one of the documents Ms. Dhillon reviewed that could have been identified and remediated. This was not the case because Madison had been instructed to ignore the deficiencies identified.
45. In an effort to follow up on the outstanding audit non-compliances relative to Nestlé that had been due and owing since July of 2022, Madison again broached the outstanding issues from the audit along with conversations⁵ that Madison had with Donna Bjurlin from Nestlé Corporate Quality with Mr. Zicher. Mr. Zicher stated again that “her expectations were not realistic and that she was being picky.”
46. On numerous occasions with numerous clients, Defendant Zicher would instruct Plaintiff to disregard certain deficiencies. Additionally, Madison had been instructed to release material that was being held for non-conformance on several other occasions.
47. Madison had raised issues and complained about violating SQF-company, customer and public policy.
48. Madison had also been in a meeting where Mr. Zicher tried to gaslight and humiliate her about not providing metrics that he was aware of that had not been supplied to Madison because they did not exist.
49. Defendant Creative Works also lacked change control management, an essential function ensuring that various requirements are being met to remain compliant with FSMA and other relevant statutes. Further, change management is directly correlated to preventive controls such as validation, verification and reanalysis relative to 21 CFR 117 §§ 160, 165 & 170. This deficiency was also noted in the July 2022 Nestlé audit CAR # 23.

⁵ A longstanding biweekly meeting was held by Nestlé to address the outstanding audit deficiencies.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

50. Prerequisite and requisite programs are required to manage such microbial hazards or any other hazards. These programs were not in place to reduce or mitigate the spread of these causative agents of food-borne diseases.
51. Defendant Creative Werks, during the relevant time did not have any Standard Operating Procedures relative to microbial hazard management or any other biological, chemical, physical or radiological hazard.
52. Defendant Creative Werks handles Ready To Eat foods, ("hereinafter RTE") that lack any further processing or kill step to eliminate or reduce hazards. Therefore, it is incumbent that a science risk-based analysis be implemented to manage identifiable and foreseeable risks to prevent food from being adulterated and introduced into the stream of commerce for human consumption (21 CFR 117).
53. It can easily be inferred that the consumer complaint filed in October of 2022 was a direct result of the lack of proper food safety and hazard analysis (risk management) at Creative Werks. The complaint was tied to cereal; a RTE.
54. More specifically, it can be reasonably inferred that the root cause of the reported October 2022 illness was due to Creative Werks' reckless and willful failure to adhere to the mandate of food safety laws and regulations relative to ensuring that food is not adulterated when it enters into the stream of commerce (21 CFR 342).
55. The company and its alter ego, the owner, Mr. Schroeder, touted a mantra of a "see something say something⁶" policy that they continuously reiterated in meetings and by post.
56. Creative Werks and its alter ego, the owner, also purported to have an open-door policy.

⁶ The FDA inspector makes note of this policy and references it in her report See Exhibit 4

13. The facts supporting the plaintiff's claim of discrimination are as follows:

57. Mr. Schroeder, the owner, on an ongoing and regular basis, spoke with his employees daily about a myriad of things. He himself espoused transparency among other things and had personally on several occasions stated that he hoped that Madison was helping the company along.
58. Madison drafted a very high-level risk analysis on October 20, 2022, in an effort to steward the compliance gaps to closure.
59. On October 21, 2022, prior to speaking with Mr. Schroeder, Madison asked to speak with Ms. Gretchen Le May, VP of People. Ms. LeMay indicated that she was not available until Monday and it was agreed that they would speak on that day.
60. On Friday afternoon, October 21, 2022, after the company's town hall meeting and luncheon, Madison spoke with Mr. Schroeder, the owner of the company regarding outstanding compliance issues and presented him with the risk analysis dated October 20, 2022.
61. Madison raised issues with Mr. Steve Schroeder regarding a known set of issues and facts regarding the September 28-29, 2022, FDA investigation of a consumer complaint of a Pepsi-Cheetos product, along with other known gaps and deficiencies of compliance, such as food safety plans.
62. During the conversation, Mr. Schroeder told Madison that Mr. Zicher told him that he worked at Kraft and he did not understand. As if to say, that Mr. Zicher working at Kraft made him more knowledgeable or the outstanding issues were obviated because Mr. Zicher had worked at Kraft.
63. Contrarily, by Mr. Zicher's own admission his LinkedIn page does not support that he ever worked at Kraft. (See Attached Exhibit 5). Further, FSMA requires that

13. The facts supporting the plaintiff's claim of discrimination are as follows:

qualified individuals have the requisite training, experience and education⁷ qualifications as defined in (21 CFR 117.3) to function in any capacity of Food Safety (21 CFR 117.4(c)).

64. Mr. Schroeder also told Madison that if her solution was to hire more people like Mr. Zicher had suggested he did not agree. Madison acknowledged that hiring more people would not fix the issues, but complying with the rules, regulations and statutes would.

65. Mr. Schroeder also indicated that {Creative Werks} was not as bad as Peanut Corporation of America.

66. Mr. Schroeder also told Madison that since she had not been there that long she should have been trying to make nice with her boss, instead of speaking with him.

67. Mr. Schroeder's conduct of telling Madison that she should have been trying to "make nice with her boss" in relation to outstanding business compliance issues is telling of the culture of Creative Werks and Mr. Schroeder.

68. Madison interpreted Mr. Schroeder's statement to mean that she should have just went along to get along no matter what. Specifically, Madison interpreted Mr. Schroeder's statement to mean that Madison should succumbed to whatever Mr. Zicher said or did because he was a man, a white man, who had allegedly worked at Kraft.

69. Plaintiff contends that telling someone to "make nice" is condescending, belittling, subservient and degrading. It is the equivalent of telling someone that they should know their place.

⁷ Mr. Zicher held himself out to be a professionally trained musician and golf pro. Mr. Zicher never represented himself as a scientist or having had any related training in the discipline of science.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

70. Mr. Schroeder is a well-educated man, holding a MBA from Johns Hopkins. He is the founder of multiple million-dollar businesses. It is unreasonable to assert that Mr. Schroeder does not know or understand proper etiquette or the connotations associated with making such a statement or the social pressures that exist that underscores Madison's takeaways from his demeaning, condescending, belittling, subservient and degrading statement to Madison. That she should have been "making nice with her boss" instead of dealing with the issues that she was hired to do.
71. Further, Mr. Schroeder knew and understood that Madison was a subject matter expert and that they both had attended Johns Hopkins for graduate school.
72. Immediately after meeting with Mr. Schroeder, Madison began to be ostracized from meetings and ignored. For example, there was a meeting with Ghirardelli, a client that Madison liaised with; she was excluded from the meeting, after receiving an email about the meeting and despite all other relevant parties being involved in the meeting, including Mr. Zicher. There was also a regulatory issue that arose relative to a salmonella outbreak at the Elk Grove facility. Madison was also excluded from this investigation. Additionally, Ms. Lemay did not meet with her as planned either.
73. This harassment and ostracizing created a hostile work environment and issues of Madison's competency internally and externally among stakeholders involved in Creative Werks' business operations. This was true especially, in view that Madison liaised with Creative Werks' customers regarding their quality and regulatory compliance.
74. Madison was retaliated and discriminated against after raising issues relative to the same contextual conversations relative to compliance gaps that Zicher had previously raised with Schroeder and others regarding the FDA investigation of a consumer

13. The facts supporting the plaintiff's claim of discrimination are as follows:

complaint along with gaps and deficiencies in compliance documents such as food safety plans.

75. On October 26, 2022, as Madison was leaving to go home, Madison was stopped by Wendy Proulx of HR, who asked Madison to step into the conference room. Ms. LeMay was there in the conference room and it was at that time that Madison was told that she was being suspended with pay for the conversation that was had with Mr. Schroeder. It was also memorialized in the suspension letter that an outside attorney would be conducting an investigation into the matters and allegations raised to Mr. Schroeder (See Attached Exhibit 6).

76. When Madison pressed Ms. LeMay on what grounds that Madison was being suspended, she stated that Madison's allegations were unfounded. Madison offered supporting evidence of her position. Madison was instructed by Ms. LeMay to save it for the attorney.

77. At no time after the conversation with Mr. Schroeder did he or anyone else follow up with Madison regarding the report. Nor was Madison involved in any type of investigation prior to being informed of Madison's suspension.

78. Madison believes that her suspension on October 26, 2022, was for impermissible reasons that included retaliation and discrimination for Madison's having presented the risk analysis to Mr. Schroeder. Madison also contends that she once again engaged in protected activity when Madison provided the risk analysis that detailed violations of the Food Safety Modernization and Bioterrorism Acts.

79. In further retaliation, Madison was not paid her signing bonus on October 27, 2022 as referenced in Madison's offer letter (See Attached Exhibit 7). Not only did

13. The facts supporting the plaintiff's claim of discrimination are as follows:

Creative Werks retaliate against Madison, it also breached its contractual agreement with Madison. Creative Werks' actions of ostracizing Madison and suspending her not only had an immediate adverse effect upon her, but it also now created a situation that interfered with her ability to be employed within this niche field.

80. After Madison insisted on counsel, she was allowed to have legal counsel.

Madison was again aggrieved, as she was only given a day or so to secure legal counsel, when in fact it had taken Creative Werks more than a week to secure the counsel, a firm that had been used on several occasions by Mr. Schroeder and his alter ego, Creative Werks LLC.

81. After Madison requested to have an attorney present at the meeting with Creative Werks outside legal counsel, Madison was further retaliated against when Madison's suspension transitioned from with pay to without pay.

82. Madison was told by Ms. LeMay that Madison did not need an attorney because this was an in-house matter and the counsel would be acting in the capacity of an independent fact finder.

83. Further, Madison also contends that being forced to meet with Ford-Harrison was a term and condition of Madison's employment. Madison also contends that it was an intimidation tactic that was harassing in nature.

84. Madison communicated to Creative Werks the adverse employment actions, which were taken against her, including but not limited to being retaliated against for identifying and raising non-compliance issues to Mr. Schroeder related to violations of FSMA. And that she had been treated differently than others who had raised the same and

13. The facts supporting the plaintiff's claim of discrimination are as follows:

or similar issues of compliance deficiencies. Madison further addressed the issue of not being afforded an opportunity to be a part of any investigation.

85. Madison was meeting Respondent's expectations as there is no other evidence to suggest otherwise. Nor had Madison been told otherwise, except for the suspension letter that specifically stated that Madison was being suspended for the conversation that Madison had with Mr. Schroeder regarding the outstanding compliance issues.

86. Defendant has engaged in a pretext to cover up its retaliatory and discriminating conduct, as well as its adverse employment actions taken against Madison. Further, Defendant did not subject Mr. Zicher to any adverse employment actions when he had conversations with them about compliance gaps or deficiencies.

87. Madison was treated differently than Mr. Zicher, by Creative Werks and Mr. Schroeder, after engaging in the same contextual conversations relative to compliance gaps. The evidence of the compliance gaps are highlighted by Defendant's need to hire Madison as a Quality Regulatory Manager, as well as, interviewing for a Regulatory Specialist.

88. Mr. Zicher further supports this contention in his July 2023 declaration in support of Creative Werks position statement to the Department of Labour stating that it hired Madison to write Food Safety Plans, which are compliance documents.

89. Following interviews and upon completion of the investigation conducted by Ford Harrison, outside counsel retained by Creative Werks, in January of 2023, contacted Madison's legal counsel to discuss settlement. The settlement would be in exchange for Madison waving any claims against Creative Werks--A Quid Pro Quo.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

90. Further, it is reasonable to contemplate that Creative Werks surmised that Madison would be in a state of vulnerability, since they had retaliated against her by suspending her without pay, and that Madison would be inclined to engage in this Quid Pro Quo because of the adverse employment actions that Creative Werks had taken.

91. Madison again requested her personnel file again pursuant to the Illinois Personnel Review Act to review the findings of the investigation that allegedly supported their contentions that Madison's assertions were unfounded.

92. Ford-Harrison, on behalf of Creative Werks declined to provide Madison's personnel file in contravention to the Illinois Personnel Review Act or the results of the investigation. (See Attached Exhibit 8). Ford-Harrison also indicated that there had not been anything added to Madison's personnel file since her request in 2022.

93. Ford-Harrison stated that Creative Werks was claiming privilege to the investigation and its findings and would not be sharing any information based on client-attorney relationship.

94. This explanation for denying Madison access to their findings that should have been contained in Madison's personnel file belies the assertion that the outside counsel from Ford Harrison was acting as an independent fact finder.

95. In response, through counsel, in January of 2023, Creative Werks was provided with various theories of causes of actions, including but not limited to retaliation, race and sex discrimination amongst other things. It was also contended that Creative Werks conspired to violate Madison's protected rights.

96. Creative Werks acknowledged that Creative Werks was aware of these theories of causes of actions relative to the series of events that had occurred between Madison and

13. The facts supporting the plaintiff's claim of discrimination are as follows:

Creative Werks. Madison was admonished by Defendant's then legal counsel to make a counteroffer, as they would not increase their offer until such time. Madison made a counteroffer and their communications ceased.

97. Further, to date Creative Werks has not and cannot point to any non-retaliatory or non-discriminatory reason for suspending Madison. Nor can Creative Werks point to any company or public policy that Madison violated relative to Madison's employment to warrant Madison's suspension and de facto discharge/termination.

98. In furtherance of the scheme to conspire to engage in pretext and in continued violation of Madison's protected rights, Creative Werks and its alter ego, Mr. Schroeder, hired an expert witness.

99. Creative Werks' expert witness further gas lighted Madison, impugning and undermining her professional reputation, characterizing her as an extremist and an alarmist. Conversely, Mr. Zicher, white male, had also raised the same contextual conversations relative to compliance gaps with Mr. Schroeder and others was not subject to such characterization nor had he been subject to any adverse employment or disciplinary actions.

100. Creative Werks' expert witness claimed to be a Food Scientist, but in reality by her own admission on her LinkedIn page is only a microbiologist⁸. (see Attached Exhibit 9)

⁸ According to the Bureau of Labor and Statistics: Food scientists and technologists use chemistry, biology, and other sciences to study the basic elements of food. They analyze the nutritional content of food, discover new food sources, and research ways to make processed foods safe and healthy. Food technologists generally work in product development, applying findings from food science research to develop new or better ways of selecting, preserving, processing, packaging, and distributing food. Some food scientists use problem-solving techniques from nanotechnology—the science of manipulating matter on an atomic scale—to develop sensors that can detect contaminants in food. Other food scientists enforce government regulations, inspecting food-processing areas to ensure that they are sanitary and meet waste management standards.

13. The facts supporting the plaintiff's claim of discrimination are as follows:

101. Further, Defendant's expert witness provided an opinion that Defendant was compliant with the Food Safety and Modernization Act. This opinion is in direct contradiction to Mr. Zicher's contention, in his July 2023 declaration, in support of Creative Werks position statement to the Department of Labour stating that it hired Madison to write Food Safety Plans, which are compliance documents.
102. Mr. Zicher's declaration stating that Madison was hired to write food safety plans; is an admission that Defendant was not in compliance.
103. These two (2) competing interests are a dichotomy that squarely supports Defendants engaging in pretext and other unlawful acts.
104. The Defendant's actions were premeditated, calculated, intentional, willful, malicious, and in reckless disregard of Madison's rights to not be further harassed, gas-lighted, or humiliated in furtherance of Defendants' contrived schemes of conspiracy, in using its Legal Counsel as an alleged fact finder and hiring an expert witness, to discriminate against Madison and to continue to violate her federally protected rights. The Defendants' actions are extreme and shocking.
105. What is even more alarming and shocking is that Defendants were knowingly willfully and recklessly operating a business in contravention of the Food Safety Modernization Act and the Bioterrorism Act of 2002. As evidence of this, adulterated food products entered into the stream of commerce resulting in consumer complaints (See

Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Agricultural and Food Scientists, at [Agricultural and Food Scientists : Occupational Outlook Handbook](#) (visited August 3, 2023).

The Bureau of Labor and Statistics defines a Microbiologist as a person who "studies microorganisms such as bacteria, viruses, algae, fungi, and some types of parasites. They try to understand how these organisms live, grow, and interact with their environments."

Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Microbiologists, at <https://www.bls.gov/ooh/life-physical-and-social-science/microbiologists.htm> (visited July 26, 2023).

Madison

13. The facts supporting the plaintiff's claim of discrimination are as follows:

Attached Exhibit 10); in addition, to the other outstanding compliance issues, identified by the FDA and other third (3rd) party audits.

106. Instead of Defendant remediating the non-compliance(s) and public safety issues, risks and hazards, Defendant, as a subterfuge, has focused a considerable amount of time and resources affixed on conspiring, harassing and discriminating against Madison.

107. Defendants intentionally, willfully and recklessly engaged in unlawful conduct and contravened public policy, by introducing adulterated food products for human consumption into the stream of commerce that created public safety risks and hazards that were harmful to consumers. (See Attached Exhibit 10)

108. The Defendant's actions were also intentional, willful, and in reckless disregard of public policy and public safety. Public policy mandates adulterated products introduced into the stream of commerce are in contravention of the Food Safety and Modernization Act and the Bioterrorism Act of 2002.

109. Defendant did not investigate or remedy Madison's complaints but treated her differently from Mr. Zicher by retaliating against her by suspending her, withholding her sign-on bonus and other benefits, and subjecting her to further harassment and other adverse employment actions including a de facto termination.

110. As a direct result of the Defendants' unlawful actions, Madison suffered emotional distress, humiliation, loss of income and benefits, and damage to her reputation and career.

16(f) additional relief sought from Court

WHEREFORE, Plaintiff, Mary Madison prays that the Court enter judgment in her favor and against the Defendants, containing the following relief:

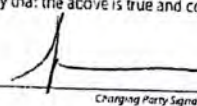
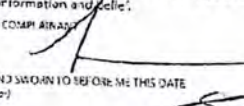
1. A declaratory judgment that the actions, conduct and practices of Defendants complained of herein violate the laws of the United States;
2. An injunction and order permanently restraining Defendants from engaging in such unlawful conduct;
3. An order directing Defendants to place Plaintiff in the position she would have occupied but for Defendants discriminatory, retaliatory and/or otherwise unlawful treatment of her, as well as to take such affirmative actions as is necessary to ensure that the effects of these unlawful employment practices and other unlawful conduct are eliminated and do not continue to affect Plaintiff;
4. An award of damages in an amount to be determined at trial, plus prejudgment interest, to compensate Plaintiff for all monetary and/or economic damages, including but not limited to, loss of past and future income, wages, compensation, job security and other benefits of employment;
5. An award of damages in an amount to be determined at trial, plus prejudgment interest, to compensate Plaintiff for all non-monetary/or compensatory damages, including but not limited to, compensation for her severe mental anguish and emotional distress, humiliation, depression, embarrassment, stress and anxiety, loss of self-esteem, self-confidence and personal dignity, and emotional pain and suffering and any other physical or mental injuries;

16(f) additional relief sought from Court

6. An award to be determined at trial for any and all other monetary and/or non-monetary losses suffered Plaintiff in an amount to be determined at trial, plus prejudgment interest;
7. An award of costs that the Plaintiff has incurred in this action, as well as Plaintiff's reasonable attorney's fees to the fullest extent permitted by law; and
8. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues of fact and damages stated herein.

EEOC Form 1 (1/69)		EEOC REC'D 21 AUG 2023		Exhibit 1	
CHARGE OF DISCRIMINATION This form is affected by the Privacy Act of 1974. See enclosed Privacy Act Statement and other information before completing this form.		Charge Presented To: <input type="checkbox"/> FEPA <input checked="" type="checkbox"/> EEOC		Agency File Charge No(s): 2024CR 0389 440-2023-09356 # 240925.038	
Name (Indicate Mr., Ms., etc.): Ms. Mary Madison		State or Local Agency, if any: and EEOC		Home/Phone (incl. Area Code): 7732979569	
Street Address: 9758 S. Charles		City, State and ZIP Code: Chicago, IL 60643		Date of Birth: 09/26/1968	
Named is the Employer, Labor Organization, Employment Agency, Apprenticeship Committee or State or Local Government Agency That I Believe Discriminated Against Me or Others. (If more than two are named, list under PARTICULARS below.)					
Name: Creative Werks, LLC		No. Employees, Members: 500+		Home/Phone (incl. Area Code): 6308602222	
Street Address: 1460 Brummel		City, State and ZIP Code: ElkGrove Village, IL 60007			
Name: Street Address: City, State and ZIP Code:		No. Employees, Members:		Home/Phone (incl. Area Code):	
DISCRIMINATION BASED ON (Check appropriate box(es)) <input checked="" type="checkbox"/> RACE <input type="checkbox"/> COLOR <input checked="" type="checkbox"/> SEX <input type="checkbox"/> RELIGION <input type="checkbox"/> NATIONAL ORIGIN <input checked="" type="checkbox"/> RETALIATION <input type="checkbox"/> AGE <input type="checkbox"/> DISABILITY <input type="checkbox"/> GENETIC INFORMATION <input checked="" type="checkbox"/> OTHER (Specify) harassment DATED DISCRIMINATION TOOK PLACE Earliest: 10/26/2022 Latest: 11/08/2022 <input type="checkbox"/> CONTINUING ACTION					
THE PARTICULARS ARE (If additional paper is needed, attach extra sheets): I was suspended on October 26, 2022 in retaliation for raising violations of the FFDCA as amended by FSMA to the owner of the company on Friday October 21, 2022. My employer provided a letter stating the same. [REDACTED] I was never a part of any investigation. I was subject to further retaliation and harassment when I was not paid my bonus that was due and owing to me on October 27, 2022. [REDACTED] I was further retaliated against and harassed when my paid suspension was converted to a suspension without pay on November 8, 2022 after telling my employer that they retaliated against me and for asking for legal counsel to attend the mandatory meeting with their outside legal counsel. I was told by my employer that they were an independent fact finder. Further, my employer conspired with outside counsel to further violate my protected rights to create a pretext. I was further harassed when I had to go to their outside legal counsel under the premise of them being an independent fact finder. On December 20, 2022, I spent over 6 hours speaking with their counsel, with over 5+ hours speaking about other issues not related to the issues that I was supposed to be speaking with them about. On January 18, 2023, the law firm indicated that my assertions were unfounded and that I could not come back to work because [REDACTED] could not work with me. On January 20, 2023, the law firm claimed privilege when I asked for the investigation findings. [REDACTED] The firm and my employer refused to share the investigation findings and my personnel file. On January 23, 2023, I informed my employer that I had been treated differently than others who had violated company and public policy; including [REDACTED] a white male. I am technically still on suspension.					
I want this charge filed with both the EEOC and the State or Local Agency, if any. I will advise the agencies if I change my address or phone number and I will cooperate fully with them in the processing of my charge in accordance with their procedures.		NOTARY: When necessary for State or Local Agency Requirements			
I declare under penalty of perjury that the above is true and correct. Date: 08/17/2023 Charging Party Signature: 		I swear or affirm that I have read the above charge and that it is true to the best of my knowledge, information and belief. SIGNATURE OF COMPLAINANT:  SUBSCRIBED AND SWORN TO BEFORE ME THIS DATE (month, day, year): 8/18/23			

DEPT. OF HUMAN RIGHTS
 INTAKE DIVISION
 09/25/2023
 RECEIVED

BY: _____

EEOC REDACTED

<<Bates Number MMAD#6#1>>



DETERMINATION AND NOTICE OF RIGHTS

(This Notice replaces EEOC FORMS 161, 161-A & 161-B)

Exhibit 2

Issued On: 9/5/2023

To: Ms. Mary D. Madison
9758 S Charles St
CHICAGO, IL 60643

Charge No: 440-2023-09356

EEOC Representative and email: NIA MOORE
Investigator
nia.moore@eeoc.gov

DETERMINATION OF CHARGE

The EEOC issues the following determination: The EEOC will not proceed further with its investigation and makes no determination about whether further investigation would establish violations of the statute. This does not mean the claims have no merit. This determination does not certify that the respondent is in compliance with the statutes. The EEOC makes no finding as to the merits of any other issues that might be construed as having been raised by this charge.

NOTICE OF YOUR RIGHT TO SUE

This is official notice from the EEOC of the dismissal of your charge and of your right to sue. If you choose to file a lawsuit against the respondent(s) on this charge under federal law in federal or state court, **your lawsuit must be filed WITHIN 90 DAYS of your receipt of this notice.** Receipt generally occurs on the date that you (or your representative) view this document. You should keep a record of the date you received this notice. Your right to sue based on this charge will be lost if you do not file a lawsuit in court within 90 days. (The time limit for filing a lawsuit based on a claim under state law may be different.)

If you file a lawsuit based on this charge, please sign-in to the EEOC Public Portal and upload the court complaint to charge 440-2023-09356.

On behalf of the Commission,

Digitally Signed By: Diane I. Smason
9/5/2023

Diane I. Smason
Acting District Director

Cc: Creative Werks

Please retain this notice for your records.

<<Bates Number MMAD#6#1>>

JB Pritzker, Governor
James L. Bennett, Director

Exhibit 3

November 2, 2023

MARY MADISON
9758 S CHARLES
CHICAGO, IL 60643

RE: Charge No.: 2024CR0389
Respondent: CREATIVE WERKS, LLC.
Complaint or Civil Action Filing Dates: **9/5/2024 through 12/3/2024**

Dear Complainant:

You have chosen to have the discrimination charge you previously filed with the U.S. Equal Employment Opportunity Commission ('EEOC') investigated by the Illinois Department of Human Rights ('IDHR') under the Illinois Human Rights Act. IDHR has received a copy of EEOC's determination and your request for the Department to investigate. A copy of the charge has been served on the Respondent. Keep this letter for reference if you need to telephone or come to IDHR.

You are required to preserve and maintain all records, including paper, electronic, or other formats, pertaining to this charge. If your charge involves the basis of disability, IDHR requires that two additional forms be completed to determine whether IDHR has jurisdiction over your identified medical condition. If we do not have copies of these documents in your file, we have included copies with this notice.

1) Verification of Disability.

Please give the Verification of Disability form to your physician for completion. Request your physician return the completed form by mail to IDHR's address below within 30 days of your receipt of this notice; and

2) Consent form.

The consent form allows IDHR to review your physician's documentation. Please fill out the consent form and return it to IDHR, again, within 30 days of your receipt of this notice.

If your charge does not involve the basis of disability, then the Verification of Disability and Consent Forms are not needed and are not enclosed.

IDHR's role is to conduct a neutral investigation of the allegations in your charge. It is your responsibility to cooperate with IDHR's investigation and provide all pertinent information you have concerning the case by the dates requested.

An investigator will contact you after the case is assigned. IDHR must complete the investigation of your case by issuing its report of findings within 365 days from the date the EEOC issued its decision on your charge. IDHR's investigation time may be extended if you and Respondent agree in writing.

555 West Monroe Street, 7th Floor, Chicago, IL 60661, (312) 814-6200, TTY (866) 740-3953, Housing Line (800) 662-3942
524 S. 2nd Street, Suite 300, Springfield, IL 62701, (217) 785-5100
2309 West Main Street, Marion, IL 62959 (618) 993-7463
www.illinois.gov/dhr

<<Bates Number MMAD#6#1>>

Case: 1:23-cv-16476 Document 1 Filed 12/04/23 Page 35 of 78 PageID #: 35
circuit court within 90 days after the expiration of the 365 days (or the extended time). We have calculated the time above (see Complaint or Civil Action Filing Dates). While we have made this calculation with the best of intentions, errors can occur. The Human Rights Commission has ruled that it is your responsibility to count the number of days properly. If you file a complaint or commence a civil action in circuit court outside this 90-day period, your complaint or civil action may be deemed untimely and dismissed.

Once 455 days (365 days [or the extended time] plus 90 days) have passed, IDHR must dismiss your charge with prejudice without any further right to proceed if you have not filed a complaint with the Human Rights Commission, or commenced a civil action in the appropriate court. Therefore, you may wish to contact an attorney to decide the best way for you to handle your case.

If you file a complaint with the Human Rights Commission, the form of the complaint must be in accordance with section 7A-102(F) of the Human Rights Act. You must serve a copy of the complaint filed with the Human Rights Commission on IDHR on the same day that you file a complaint with the Commission. The Human Rights Commission will then schedule a hearing for your case before an Administrative Law Judge.

If you commence a civil action in circuit court, the form of the complaint must be in accordance with the Illinois Code of Civil Procedure. Please also serve a copy of your complaint on the EEOC: 500 West Madison Street, Suite 2000, Chicago, IL 60661. If you file a complaint with the Commission, you may not later commence a civil action in circuit court.

You must advise IDHR of all changes of name, address, or telephone numbers. If you do not do so, IDHR may dismiss your case if it cannot locate you.

SB1122 IN-6 Non-Med
CR/SR
4/17

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Summary

This pre-announced comprehensive routine surveillance inspection of a warehouse, packer/repacker, labeler/Relabler and distribution center (DC) was performed as part of HAF 6 EAST FY-2022 Workplan in MARCS/eNSpect as OP ID-#226878. This

inspection was accomplished utilizing CFR-21, Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Control for Human Food – Subparts A, B, and F along with Compliance Program 7303.040, Preventive Controls and Sanitary Human Food Operations. In addition to CP 7321.005 Domestic NLEA and General Food Labeling Program.

Creative Werks LLC functions as a warehouse, packer, repacker (Co-Packer), labeler, Relabler, and DC. The firm's top three customers are (b) (4). The firm's top three products at this location are (b) (4).

This firm store, packs/repacks (Co-Packs), labels/relabels a variety of wrapped and unwrapped ready-to-eat food products per their customer request. After packing/repacking, labeling/relabeling and final packaging is completed, the finished product is scheduled to be shipped to one of their customers distribution centers as specified by their customer.

Previous inspection

The firm has never been inspected by the Agency. This was the firm's initial inspection.

Current Inspection

This inspection was classified as NAI. Although, the firm was not issued an FDA Form 482 at the close of this inspection. The following concerns were discussed in detail with management as follows:

1. I observed light seeping through dock door #5 during the walk-through.
2. I observed that the firm is not consistent with recordkeeping after reviewing training documents.
3. I observed that the consumer complaint investigation for consumer complaint #170623 should have had a faster response.
4. I observed that the firm's pest control activities are inconsistent and needs work.
5. I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top.

Management Response:

Mr. Zicher promised to make corrections to the observations as soon as possible.

This inspection focused on the following areas: Sanitary Transport, Sanitation, Raw Materials, Recalls, Customer Complaints, Pest Control, Quality Control, Sales, Production, Purchasing, Recordkeeping, and Employee Training.

I did not notice any avian, insect and/or rodent activity during the inspection.

I did not take any samples and/or photos during this inspection.

(b) (3) (A)

I did encounter one refusal during this inspection which converted to an electronic view of consumer complaint #170623 for closure.

Consumer Complaint #170623 Follow-up – (b) (4)

(b) (4) Cheese Snacks- 20 ounce (1.4 rigid plastic container with screw chalking).

Product of (b) (4)

Consumer Complaint: This consumer complaint dealt with a consumer becoming ill after consuming (b) (4) Cheese Snack. The customer identified a black substance found around the lid as mold.

Corrective Actions as provided by the firm (Identification of Root Cause):

Issues	Resolution	Date Accomplished
Slippage experienced with the lid torque.	Custom built machine chuck was installed to replace the silicone rubbing head & reduce any slipping in the lid application.	3/22/2021
Multiple passes with a barrel through the induction sealer caused burning of the film stock.	Production Team discontinued sending barrels through the sealer more than once.	5/20/2021
Settings for induction sealing equipment not documented.	Documented settings were recorded & posted on the line for the Maintenance Team.	6/6/2021
Reject cylinder & rails caused barrels to jam.	Section of rail was removed to prevent jars & counting sensors was relocated.	6/7/2021
Lid cocked sensor process had poor repeatability.	Adjusted & documented location of cocked lid sensor. Tested in various orientations.	6/6/2021

Additional Complaints: According to Mr. Erich P. Zicher, Director of Food Safety the firm had only one similar complaint sent by (b) (4) on March 13, 2022 regarding a burnt seal. In addition, Mr. Zicher told me he was not aware of any other complaints.

Findings: According to the firm's findings the induction seal for the lid was burnt due to multiple entries of the lid passing through the induction (heat) sealer. It was documented that during manual application of the lid the firm experienced jams on the production line which also resulted in burnt lids.

Packaging Procedure: The packaging procedure for this product was modified on May 20, 2021 as document in the firm's step-by-step corrective actions/investigation listed above.

Preventive Controls: The firms preventive control consisted of the removal of manual application of the lid to a (b) (4) lid application to remove the variation out of manually applying the lid. According to the firm the new machinery was approved by (b) (4)

Product's Current Disposition: According to Mr. Eric P. Zicher, Director of Food Safety, the firm currently is not repacking (b) (4) Cheese Snacks for (b) (4). The contract for packing this product is stagnant until there is a negotiated procedure for lid application for this ready-to-eat product.

Administrative Data

FMD-145

A copy of this EIR should be sent to the individual listed below:

Mr. Erich P. Zicher, Director of Food Safety
Creative Werks, LLC
1460 Brummel Avenue
Elk Grove Village, IL 60007
Email address: ezicher@cwerksglobal.com

Inspected Firm: Creative Werks, LLC
Location: 1350 Munger Rd.
Bartlett, IL 60103

Phone: (630) 860-2222

Fax: None

Mailing Address: 1460 Brummel Avenue
Elk Grove Village, IL 60007

Email Address: ezicher@cwerksglobal.com

Dates of Inspection: September 28, 2022 & September 29, 2022

Days in Facility: 2-Days

Participant: Clotia C. Abbey-Mensah, Investigator

On September 28, 2022 I presented credentials and issued an FDA Form 482 Notice of Inspection to Mr. Eric P. Zicher, Director of Food Safety who identified himself as the person most-in-charge. We were joined by Ms. Angela K. Knabe, Quality Regulatory Manager, Ms. Anupam (N.M.I.) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. Throughout this inspection I was provided documents for review as requested by Mr. Zicher and Ms. Sharma. I was accompanied on a tour of this facility by Mr. Zicher and Ms. Sharma.

History

Creative Werks is located at 1350 Munger Rd. in Bartlett, IL 60103 in DuPage County. The firm is owned by Mr. Steven A. Schroeder, President. I asked Mr. Zicher if Mr. Schroeder maintain an office at this location and he responded no. The firm has been in business since 1999 and at this location since May 2015.

The firm is (b) (4) square feet (sq. ft.). Of this square footage (b) (4) is considered manufacturing per Mr. Zicher. This firm store, packs/repacks, labels/relabels a variety of wrapped and unwrapped ready-to-eat food products per their customer request.

The firm's telephone is (630) 860-2222. The firm has (b) (4) employees at this location. This number includes hourly, salary and temporary employees per Mr. Zicher.

The firm has two other locations as listed below:

Headquarters/Production Facility	Warehouse/Production Facility
Creative Werks, LLC	Creative Werks, LLC
1460 Brummel Avenue	222 Sievert Court
Elk Grove Village, IL 60007	Bensenville, IL 60106

The firm's office hours are 8:00 am to 5:00 pm Monday – Friday. The firm's production hours are (b) (4) according to Mr. Zicher. The shifts are scheduled as follows:

(b) (4)

The firm runs manufacturing and co-packing on all (b) (4) shifts per Mr. Zicher. The firm does not have scheduled shutdowns for preventative maintenance. According to Mr. Zicher one of the firm's main functions is private labeling.

The firm's FY starts on January 1st and ends December 31st annually. The firm's website is www.creative-werks.com. The firm's email address is ezicher@cwerksglobal.com.

Interstate (I.S.) Commerce

I asked Mr. Zicher what percentage of the finished products at this location cross state lines. He responded (b) (4). I asked what percentage of the finished product is sold wholesale. He responded (b) (4). Lastly, I asked what percentage of components are received through interstate and he responded (b) (4). I requested a copy of a BOL for (b) (4) which was not provided.

The firm does business with their customers Distribution Centers (DCs) domestically and internationally as listed:

1. California
2. Georgia
3. Indiana
4. New Jersey
5. Pennsylvania
6. Texas

7. Utah
8. Wisconsin
9. Alberta – Canada (Calgary)
10. Ontario – Canada (Brampton)
11. Ontario – Canada (Mississauga)

Jurisdiction (Products Manufactured and/or Distributed)

This firm packs/repacks, labels/relabels a variety of ready-to-eat food products such as chocolate candy, cereal, chewing gums and snack foods etc.

Individual Responsibilities and Persons Interviewed

On September 28, 2022 I presented credentials and issued an FDA Form 482 Notice of Inspection to Mr. Eric P. Zicher, Director of Food Safety who identified himself as the person most-in-charge. We were joined by Ms. Angela K. Knabe, Quality Regulatory Manager, Ms. Anupam (N.M.I.) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. Throughout this inspection I was provided documents to review as requested by Mr. Zicher and Ms. Sharma. I was accompanied on a tour of this facility by Mr. Zicher and Ms. Sharma. I requested a copy of the firm's organizational chart during this inspection. (See Exhibit #1)

Responsibilities:

Mr. Eric P. Zicher, *Director of Food Safety*

- Food Safety & Quality
- Escalates Issues
- Environmental Issues
- Projects – (Ongoing, New)
- Identifying Potential Quality Risks
- Microbiological Aspects with Products
- Write SOPs (Work Instructions, Policies, etc.)
- Hire/Fire
- Strategic Directives for Container Safety
- Food Safety & Quality
- Time with firm: 1.9 years
- Time in current position: 1.9 years
- Direct Reports: [REDACTED]
- Reports to: Mr. Ronald Sammeth, *Chief Operating Officer*

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Creative Werks, LLC
Bartlett, IL 60103

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EI Start Date: 09/28/2022
EI End Date: 09/29/2022

Ms. Angela K. Knabe, *Quality Regulatory Manager*

- Audits (Clients POC for Audits)
- Lead Good Manufacturing Practice (GMPs) Walk
- Ensuring Compliance (Corrective Actions)
- Vendor Approvals
- Quality Management Systems - (PCQI)
- Time with firm: 3.5 years
- Time in current position: 2 years
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Ms. Anupam (N.M.I.) Sharma, *Food Safety & Quality Manager*

- Discussion of Food Safety holds with Sales Personnel
- Certificate of Analysis (COA) Reviews
- Packaging Reviews
- Raw Materials Packaging; Film Review
- Hold Releases
- Operational aspects within Specifications
- Timecards
- Employees Issues
- Releasing product after review of COA
- POC for Food Safety /Food Compliance
- Assist with SOPS by other departments
- GMP Training provided to Operations, Sanitation Materials Handlers and Quality Control Employees
- Sending out samples for testing
- Time with firm: 1 year
- Time in current position: 1 year
- Direct Reports: [REDACTED]
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

Ms. Mary D. Madison, *Quality Regulatory Manager*

- Audits (Clients POC for Audits)
- Lead Good Manufacturing Practice (GMPs) Walk
- Ensuring Compliance (Corrective Actions)
- Vendor Approvals
- Quality Management Systems - (PCQI)
- Time with firm: 2 days
- Time in current position: 2 days
- Reports to: Mr. Eric P. Zicher, *Director of Food Safety*

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Firm's Training Program

I asked if the firm provide any training to their employees and the response was yes. Training is provided to employees upon hire and annually. Ms. Sharma told me that the firm use (b) (4) software for training. The software divides the various training modules into specific topics such as Food Safety, Foodborne Illnesses, Guidance Principles etc. I asked Ms. Sharma if the employees sign-off on training and she responded yes. During this inspection I randomly reviewed employees training records that appeared to be adequate except the firm's recordkeeping is not consistent. All employees do not consistently sign-off on training records as required in their own procedure with a signature and date, which is deemed an official document. This observation was shared with Ms. Sharma during this inspection. This was an observation previously observed at the firm's Elk Grove Village facility.

I requested a copy of management training records during this inspection. (See Exhibit # 2)

Manufacturing Design Operations

This firm packs/repacks and labels/relabels ready-to-eat products such as candy, cereal, cookies, and gums, etc. for their clients.

Donning Area/ Handwashing Station

Prior to entering the manufacturing area, a visitor is required to wear the following PPE: hairnet, ear plugs, laboratory coat, safety vest and safety goggles. The firm identifies individuals in production as follows:

(b) (4)		
Management	Visitors	Quality Control

After donning is completed, you proceed to the handwashing station, located adjacent to the employee's break room.

Ambient Warehouse

The firm's warehouse aisles on the south-side mid-way are labeled (b) (4) The north-side of the aisles are labeled (b) (4)

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Dock Doors

The firm has (b) (4) dock doors at this location. Two of the (b) (4) are not in use. Dock Door (b) (4) contains the firm's compactor. Dock Door (b) (4) is used to store equipment. The firm's dock doors are grouped into (b) (4) as follows: (b) (4) and (b) (4). I observed that dock door #5 has sunlight seeping in. I shared this observation with Mr. Zicher and Ms. Sharma during the walk-through.

Production Area

The firm has (b) (4) active production lines. Currently the firm is actively using (b) (4) production lines. Some production lines are in segregated rooms. Some production areas can have several production lines packing a variety of products in the same room.

The firm's sanitation area is (b) (4). I observed a walk-in equipment washer from the outside looking in. The doors to this area were locked but I could see from the outside mostly covered cleaned production parts and equipment.

Lines (b) (4) – Repacking

I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top. This observation was immediately shared with Mr. Zicher and Ms. Sharma during the walk-through. I noticed a similar action with a production employee at the firm's Elk Grove Village location.

This area is also used for storing production equipment and supplies.

I observed (b) (4) packed on these lines in a clear plastic holiday cane. (See Exhibits #3-5)

Sanitation Area

In the next section of the contained sanitation area, I could see compartment sinks. I observed a (b) (4) compartment sinks. I asked what the (b) (4) compartment sink is used for. I was told it is used for washing and sanitizing. There appears to be no rinse step for the (b) (4) compartment sink. I could also see (b) (4) frosting pump equipment through the exterior sight windows.

The east wall in this area houses the maintenance department, and employee entrance.

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Line (b) (4) – Whole Packing

I observed (b) (4) Tubes packed on this production line.

Line (b) (4) (Naked)

I observed naked (unwrapped) candy been packed in tubes on this production line. The tubes are equivalent to clear plastic candy canes.

Line (b) (4)

I observed (b) (4) been packed in the cereal room.

Lines (b) (4) Line)

I observed (b) (4) candy containing peanuts repacked on this production line. The firm only runs peanut production on these lines.

Line (b) (4)

This line packs chewing gum. It was currently not in operation during the walk-through.

Lines (b) (4)

I observed (b) (4) packed on these lines in a clear plastic holiday cane.

HACCP Plan

I asked Mr. Zicher if the firm has a HACCP Plan and he responded yes. Ms. Angela K. Knabe, Quality Regulatory Manager is responsible for the firm's Quality Management System (QMS). Time did not permit me to verify the firm's entire food safety plan during this inspection. Ms. Knabe identified herself as the firm's PCQI. This responsibility will soon be delegated to Ms. Mary D. Madison because Ms. Knabe is leaving the firm next week. The firm also have x-ray equipment in place as a process preventive control.

Metal Detectors

The firm documents their metal detector every (b) (4). This information was not verified. This is the firm's only critical control point (ccp) in their process. The firm's metal detectors are calibrated by (b) (4), located at (b) (4). Their telephone number is (b) (4). The firm's website is (b) (4).

Leak Detector

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I asked Mr. Zicher if the firm performs leak detection at this facility and he responded yes. The leak detection is performed on the cereal production line. This information was not verified.

Raw Materials

The firm's raw materials consist of clear plastic candy canes, cane handle, product labels for packaging, wrapped candy products, plastic bags, cereal bowls, cardboard boxes, etc.

Allergens

I asked management if the firm has any allergens onsite and their response was yes. The allergens consist of eggs, wheat, soy, dairy, peanuts, and tree nuts per Ms. Sharma. The firm may handle allergens contained in wrapped or unwrapped packaging. I asked Mr. Zicher what preventive controls are in place to prevent cross contamination. He responded sanitation is used to prevent cross contamination and production takes place in cycles. The firm also performs ATP swabbing prior to production per Ms. Sharma. This information was not verified.

Internal Audits

I asked Mr. Zicher if the firm performs internal audits, and he responded yes. The firm performs internal audits annually. This information was not verified. In addition, Ms. Knabe told me that she leads GMP (b) (4) walking audits of the facilities and Food Safety meetings.

Sanitation

I asked Mr. Zicher if the firm has a Sanitation Standard Operating Procedure (SSOP) and he responded yes. I randomly reviewed the firm's SSOP- #6.15 effective June 21, 2022, and it appeared to be adequate. I asked who provides sanitation training and I was told Supervisors, Assistant Supervisors and Team Leads.

Sanitary Transport

The firm has a sanitary transport SOP WI-5,2 that includes (b) (4)-conditions which is uploaded into their database via their (b) (4) software. After review of the firm's sanitary transport SOP, it appears to be adequate.

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Logistics

The firm's customers broker trucks for transporting their products. The customers arrange product loads inbound and outbound of their facility. Some customers use their own fleet of trucks. Regardless per Mr. Zicher the truckers must make appointments for pick-ups and deliveries.

Environmental Controls

I asked management if the firm has an environmental control program, and the response was yes. I reviewed the firm's SOP and it appeared to be adequate. The firm's program is sectioned into [REDACTED]-Zones. Zone [REDACTED] (food contact surfaces) per Ms. Sharma is cleaned and sanitized. The firm sends out samples for APC and E. coli as validation for sanitation. Zones (b) (4) are swabbed with sponges and sent out for Salmonella and Listeria species testing. The samples are sent to (b) (4) (b) (4) located in (b) (4). I asked who performs the swabbing and Ms. Sharma responded the Quality Supervisor, Team Lead and Quality Manager.

Water

I asked Mr. Zicher if the firm monitor the water for the city of Bartlett. Mr. Zicher responded yes. A copy of the city's annual test results was shared on the firm's overhead screen. Additionally, the firm collects and sends out (b) (4) water samples for Heterotrophic and coliforms.

Refuse

The firm's refuse is serviced by (b) (4) is located at (b) (4) (b) (4). The firm's telephone and website are (b) (4) and (b) (4) respectively.

The firm's recyclables and landfills are also maintained by (b) (4). The recyclables consist of corrugated and plastics polymers such as (b) (4).

Manufacturing Codes

I asked Mr. Zicher to decipher the firm's manufacturing code as follows:

(b) (4)

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(b) (4)

(b) (4)

Complaints

I requested a copy of the firm's consumer complaint procedure during this inspection for review. The firm's consumer complaint is identified as WI-2.6 with an effective date of May 21, 2019. The firm's complaint procedure appears to be adequate. I asked Mr. Zicher if the firm performs trending, and he responds yes. Because the firm co-packs for their clients there is a relationship between Creative Werks Quality personnel and their client's Quality Contact per Mr. Zicher. I asked how investigations are performed. Mr. Zicher told me that after an investigation is completed a corrective action is provided when the root cause is determined.

Recall Procedures

The firm has a recall procedure reference as Traceability. According to Ms. Sharma the firm performs trackabilities (b) (4). I randomly reviewed the procedure, and it appears adequate. I asked management if the firm performs Mock Recalls and Ms. Sharma responded yes. This information was not verified. She told me that the firm performs traceback and trace forward.

Objectionable Conditions and Management Responses

The following members of management were in attendance during the close-out meeting: Mr. Eric P. Zicher, Director of Food Safety, Ms. Anupam (N.M.I.) Sharma, Food Safety & Quality Manager, and Ms. Mary D. Madison, Quality Regulatory Manager. In addition, we were joined by Mr. Ronald Sammeth, Chief Operating Officer on the telephone. This inspection was classified as NAI. Although, the firm was not

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issued an FDA Form 482 at the close of this inspection. The following concerns were discussed in detail with management as follows:

1. I observed light seeping through dock door #5 during the walk-through.
2. I observed that the firm is not consistent with recordkeeping after reviewing training documents.
3. I observed that the consumer complaint investigation for consumer complaint #170623 should have had a faster response.
4. I observed that the firm's pest control activities are inconsistent and needs work.
5. I observed a production employee cleaning equipment located along the north wall adjacent to Production Line (b) (4) with a long white towel using his right hand to touch the floor for balance and alternating the towel in his right hand as he cleans the conveyor equipment on top.

Management Response:

Mr. Zicher promised to make corrections to the observations as soon as possible.

Refusals

I did encounter one refusal during this inspection which converted to an electronic view of consumer complaint #170623 for closure.

General Discussion

I requested a copy of the firm's Consumer Complaint Procedure. Instead, I was provided a copy of the firm's Customer Supplied Materials Procedure via email on September 28, 2022. (See Exhibit #6) I reviewed this procedure, and it was not easy to read or understand. N.B.-This procedure revision numbers are incorrect and annual reviews list the same revision numbers although they were reviewed in completely different years. The current revision number should be 12 instead of 6.

Revision Number	Effective Date	Revision Log	Approved By	Approved Date
4.0	9/15/11	AR/NC	(b) (6)	9/14/2011
4.0 = 5.0	11/26/12	AR/NC		11/24/12
4.0 = 6.0	02/21/14	AR/NC		2/19/14
4.1 = 6.1	4/07/14	Changed Procedure		4/5/14
6.0 = 12	07/22/21	Updated	Erich Zicher	07/16/21

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Ledger: AR = Annual Review; NC = No change

Additional Information

Pest Control

The firm's pest control is monitored by (b) (4) is located at (b) (4). Their telephone number is (b) (4).

The firm is concerned with rodents and insects. The firm's preventive controls consist of (b) (4) traps, (b) (4) and (b) (4) traps. I randomly reviewed the firm's pest control records from January 2022 to August 2022.

The firm's pest control records indicated that there is no consistent follow-up between the firm and the pest control technician after the service is completed. This issue appears to be ongoing for quite some time. I asked Mr. Zicher if the firm has considered replacing this pest control company due to a lack of genuine service capabilities. Mr. Zicher responded that it has been considered.

Parking/Entry:

FYI! - The facility's visitor's parking is limited. In addition, the signage for visitor's parking is in an inconspicuous location. It's attached to the entry area façade of the building much higher than normal posting therefore, making it easy to overlook. NB: Prepare to locate available parking anywhere in the firm's parking lot.

The entry area is a virtual set-up. If you are equipped with the Director of Food Safety's cell number, please use it for prompt entry.

Food Defense:

The firm's culture regarding Food Defense consists of "see something, say something" per management. In the firm's employee badging and entry area the firm is equipped (b) (4). But the main entry into the building (b) (4) (b) (4). On September 28, 2022, I was allowed entry into the facility without signing in because there were no sign-in sheets available. I was told its okay. On September 29, 2022, the same scenario, I told the escort there were no sign-in

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sheets available. This time that individual returned with a sign-in sheet. The firm's business entry is easily accessible due to (b) (4) through the lobby door. Management should be aware and concerned about who enters their facility and their whereabouts upon entry.

Samples Collected

I did not take any samples and/or photos during this inspection.

Voluntary Actions

I did not witness any voluntary actions during this inspection.

Exhibits Collected

1. Organizational Chart
2. Management Training Certs – 3 pages
3. (b) (4) – 2 pages
4. (b) (4) Labels
5. (b) (4) Candy Wrappers
6. Consumer Complaint Procedure (Customer Supplied Materials) – 3 pages

Attachments

1. FDA Form 482 Notice of Inspection dated September 28, 2022 – 3 pages

10/18/2022

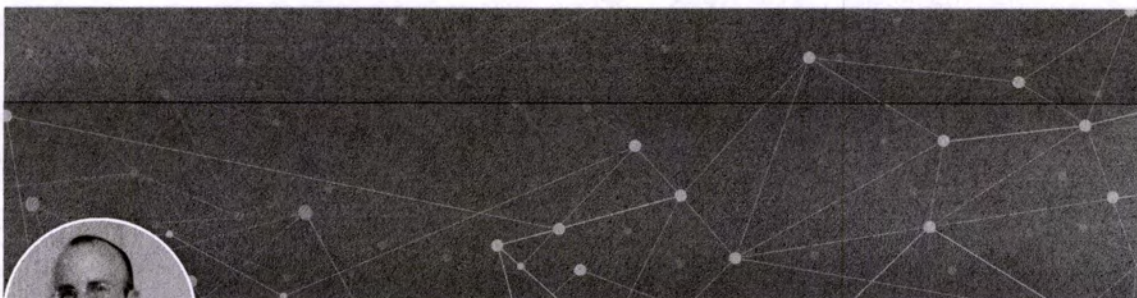
X Clotia C. Abbey-Mensah

Clotia C. Abbey-Mensah

Signed by: Clotia C. Abbey-mensah -S




Exhibit 5

**Erich Zicher**

Quality Assurance; Food Manufacturing; Lean Management; FDA; USDA; HACCP; PCQI

Schaumburg, Illinois, United States

729 followers · 500+ connections

[Join to view profile](#) creative werks, llc Arizona State University

Activity

The New Leadership

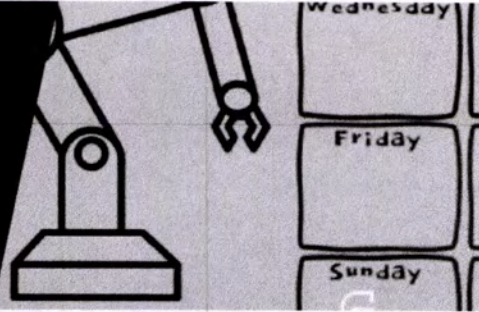
KPI**Keep people interested**

this is a no-brainer...you don't achieve KPIs unless you achieve the following other "KPI"s...
then it falls into place naturally.

Liked by Erich Zicher



4 Types of Innovation All Packaging Departments Should Know



So happy to be able to lend some insight into innovation for this article! Special thanks to @PackagingDigest for publishing my piece on innovation....

Liked by Erich Zicher



Degrees have **officially** conferred at ASU (a month later) and I'm officially an alumni now! So beyond thrilled to have this behind me and my future...

Liked by Erich Zicher

Join now to see all activity

Experience



Director of Food Safety

creative werks, llc

Nov 2020 - Present · 2 years 3 months

Elk Grove Village, Illinois, United States



Quality Assurance Manager

Hearthside Food Solutions / Greencore

May 2017 - Jan 2020 · 2 years 9 months

Carol Stream, IL



Oct 2017 - Apr 2018 · 7 months

United States

PEACOCK FOODS / GREENCORE



5 years 4 months

Quality Assurance Manager

Sep 2013 - May 2017 · 3 years 9 months

Bolingbrook, IL

Quality Assurance Supervisor

Feb 2012 - Sep 2013 · 1 year 8 months

Bolingbrook, IL



Alpha Baking

2 years 9 months

Director of Sanitation

Nov 2009 - Feb 2012 · 2 years 4 months

Greater Chicago Area

Director of Quality Assurance

Jun 2009 - Nov 2009 · 6 months

Education



Arizona State University

Bachelor of Science - BS



Harper College

Associate of Arts - AA



AIB International

-



Eastman School of Music

BA (3 years complete)

1999 - 2002



John Hersey High School

-

**A3 Problem Solving for Continuous Improvement**

LinkedIn

Issued Mar 2021

See credential**Preventive Controls Qualified Individual**

Food Safety Preventive Controls Alliance (FSPCA)

Issued Sep 2016

Credential ID 75d90fbc

Implementing SQF Systems (Post Farm Gate)

SQF Institute

Issued Feb 2014

Credential ID A0011893

Food Safety and Sanitation for Food Plants

AIB International, Inc

Issued Jan 2011

Food Processing Sanitation/Hygiene

American Institute of Baking

Issued Sep 2010

HACCP

International HACCP Alliance

Issued Sep 2010

Credential ID (renewed September 2015)

10-hour Occupational Safety and Health Training

OSHA

Issued Jul 2010

Recommendations received**Matt Burke**

"Erich is the type of manager that you learn from daily. He is very hands on with his staff and continuously pushes them to reach their potential. His attention to detail and drive to learn makes him a major asset to any company. The best part about working with Erich is his positive attitude and his willingness to stop anything to help fellow colleagues. I valued my time spent with Erich as my manager."

1/18/23, 11:55 AM

Erich Zicher - Director of Food Safety - creative werks, llc | LinkedIn



and standardizing work. He consistently demonstrated a solid work ethic and sense of urgency. We collaborated on an ERP system roll out across multiple sites in my division and he was instrumental in the training of staff for implementation. Erich is dedicated, self-motivated, methodical and reliable. He is not only a forward thinking Department Manager but also inspirational in his enthusiasm."

3 people have recommended Erich

Join now to view

More activity by Erich

Proud to be a part of this incredible team! 🏆

Liked by Erich Zicher

7 years as a FA with United, 5 years of flight training, instructing and time building, many struggles and tears, I finally able to make the...

Liked by Erich Zicher

Come see me at Booth# 1665! I'll be here all afternoon at IFT First! #iftfirst #IFT #chicago

Liked by Erich Zicher

View Erich's full profile

<<Bates Number MMAD#6#1>>

1/18/23, 11:55 AM

Erich Zicher - Director of Food Safety - creative werks, llc | LinkedIn



Contact Erich directly

Join to view full profile

d

j & Maintenance at creative werks, llc

it Services and Information Technology at creative werks, llc

3

ty Manager

ufacturing and Engineering at Creative Werks LLC

ety & Quality Assurance Professional

A

l Manager at creative werks, llc

Supervisor | Warehousing | Logistics | Program Management | Quality Assurance / CAPA /
ients | Change Agent

idual with Quality Control and operations experience looking for an opportunity to add
rough learning and demonstrating exceptional work ethic and team work.

anager at creative werks, llc

vate Label and Brand Project Development and Management; Operations Continuous

1/18/23, 11:55 AM

Erich Zicher - Director of Food Safety - creative werks, llc | LinkedIn



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Our Android App for Kotlin Developers

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Structures: Sets and Frozen Sets

e badge

on other websites

Food Manufacturing; Lean Management; FDA; USDA; HACCP; PCQI

at creative werks, llc

y

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- Language



creative werks

1470 Brummel Ave
Elk Grove Village, IL 60007

www.creative-werks.com
630.860.2222

Exhibit 6

Notice of Suspension

October 26, 2022

Mary Madison
Quality Regulatory Manager
Via Hand Delivery

Dear Mary,

This letter is to inform you that you are being placed on a paid suspension effective immediately. This suspension will last until a full investigation into the statements made in your report and during your conversation with Steve Schroeder on Friday, October 21, 2022 can be fully completed. This review will be conducted by an outside attorney and Human Resources will make the introduction when the time comes.

During your suspension you will be paid at your regular rate of pay and have access to benefits. You will not have access to any IT systems or the building until the investigation is complete.

If you have further questions, please reach out the HR team as needed.

Thank you,

Gretchen LeMay
Head of People



1470 Brummel Ave
Elk Grove Village, IL 60007

www.creative-werks.com
630.860.2222

September 20, 2022

Mary Madison,
Via Paycor- assist2law@gmail.com

Dear Mary,

I am very pleased to offer you the opportunity to join our team at creative werks. We believe that you will find working at creative werks challenging, fun, and a great opportunity to learn. Fit is key for us and we believe that your contributions and work ethic will help our Company grow and flourish.

We would like to confirm the arrangements made regarding this opportunity. We are very happy to offer you a position as a **Quality Regulatory Manager**, at our **Elk Grove Village** location on **1st Shift** within our **Quality** department. This position will be reporting to Erich Zicher (Food Safety Director) starting on September 27, 2022.

Compensation

- You will be paid a Salaried Exempt rate of \$3,653.85 paid bi-weekly (\$95,00 annually) so long as you are actively employed by the Company.

Annual Incentive Plan (AIP)

- You will be eligible to participate in creative werks 2023 Annual Incentive Plan (AIP) with a target incentive of 10% of your salary. The AIP is based on a combination of company performance, individual performance, and target incentive. The 2023 AIP will be payable in March 2024. Please refer to the AIP document for specific plan details.
- As discussed, we are pleased to offer you a signing bonus of \$2,500 payable in one lump sum on October 27, 2022. This signing bonus is taxable, and all regular payroll taxes will be withheld. In the event that you leave creative werks within 12 months of your date of hire, you will be responsible for reimbursing the company for the entire signing bonus. By your signature on this employment agreement, you authorize the company to withhold \$2,500 from any severance and other final pay you receive should your employment terminate on or before October 27, 2023

Paid Time Off (PTO) and Holiday Pay

- You will accrue PTO at the rate of 16 days per year (2.46 hours per week).
- For 2022, since you are starting later in the year, you will be eligible for 4.5 days of PTO.
- As a CW associate you will receive 9 paid holidays throughout the calendar year.



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630.860.2222

Code of Ethics, Values and Policies

- creative werks is committed to creating a positive environment and conducting business ethically. As an associate of the Company, you will be expected to abide by our Guiding Principles and general policies and practices set forth in our Employee Handbook.

After you return this signed offer letter, you will receive two emails from Paylocity. Paylocity is our onboarding tool which contains various online documents such as benefit forms, tax forms, a participation release form, an emergency contact form, confidentiality agreements, a background check, an employment eligibility form (I-9), and information about the Health Insurance Portability and Accountability Act. Please complete these documents as soon as you can. We need these completed in advance of your start date so we can be prepared for you when you arrive.

Please note that this offer is contingent upon successful completion of the background check and compliance with all new hire forms.

Mary, your signature below will acknowledge that there have been no representations by the Company or its agents which are not reflected in this letter. Please review all terms of this letter, returning the signed original to me by September 23, 2022

I am pleased you have decided to join creative werks. I look forward to watching your progress with the Company.

Sincerely,

Gretchen LeMay

Gretchen LeMay
Head Of People / Corporate VP

Mary Madison1 cef

Mary Madison

September 20, 2022

Date



Exhibit 8

Mary Madison: Statement; Risk Analysis and Personnel File Requests

1 message

Craig R. Thorstenson <CThorstenson@fordharrison.com>
To: Jordan Hoffman <jthoffmanlaw@gmail.com>

Fri, Jan 20, 2023 at 9:53 AM

Hi Jordan

I've asked Creative Werks to pull together Madison's personnel file and will provide them to you. She specifically asks for the investigation findings in her request. We will not be providing any investigation report or findings because they are subject to the attorney client privilege.

[Quoted text hidden]

ATTORNEY WORK PRODUCT - PRIVILEGED & CONFIDENTIAL

The information contained in this message from Ford & Harrison LLP and any attachments are privileged and confidential and intended only for the named recipient(s). If you have received this message in error, you are prohibited from reviewing, copying, distributing or using the information. Please contact the sender immediately by return email and delete the original message and attachments. In the absence of an executed engagement letter or fee contract, no attorney client relationship is established by this communication.



Mary Madison: Statement; Risk Analysis and Personnel File Requests

1 message

Jordan Hoffman <jthoffmanlaw@gmail.com>

Fri, Jan 20, 2023 at 10:59 AM

To: Craig R. Thorstenson <CThorstenson@fordharrison.com>

Good morning, Craig. Thank you for your response. Surely, the attorney-client privilege doesn't extend to the in-house communications between the decision makers that are in Ms. Madison's file relative to Creative Werk's preliminary investigation that lead to her suspension.

Jordan

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[Quoted text hidden]

Contact

www.linkedin.com/in/kathyknutsonphd (LinkedIn)

Top Skills

Food Science
Microbiology
Food Safety

Languages

Latin (Limited Working)
German (Elementary)

Certifications

Teaching Certificate - Family and Consumer Science, Foods
Sanitation Manager
Food Safety HACCP Manager
Lead Instructor

Publications

Hazard Analysis and Critical Control Points (HACCP) for the Cannabis Industry
Knutson KM, Marth EH, Wagner MK. Important milestones in the history of milk pasteurization. Dairy Food Sanit. 1987. 7:459
Overview of the FDA juice HACCP rule
Microbiology 101 Part 1
Juice HACCP Training Curriculum

Kathy Knutson, Ph.D., PCQI, HACCP-certified

Food and Cannabis Consultant | PCQI Coach & Lead Instructor
| Author of "Food Safety Lessons for Cannabis-Infused Edibles" |
Chair, Education Committee, National Cannabis Industry Association
Green Bay, Wisconsin, United States

Summary

If you are in the food or cannabis industry, I want to network with you! I am a microbiologist with expertise in food safety. I travel nationally and globally to consult side-by-side with manufacturers on recall investigations, risk assessments, problem-solving, training, and Food and Drug Administration (FDA) compliance. I trained to be a Lead Instructor with the FDA-recognized curriculum for Preventive Controls Qualified Individuals (PCQIs) in 2016. At last count, I have delivered 40+ PCQI workshops training 500+ PCQIs.

With 35+ years in microbiology and 15 years of full-time teaching, I am passionate about training and can effectively communicate at all levels in an organization from line operator to CEO. I have taught and consulted with companies on laboratory methods, interpretation of lab results, quality assurance, sanitation, environmental monitoring, Standard Operating Procedures (SOPs), Good Manufacturing Practices (GMPs), Hazard Analysis and Critical Control Points (HACCP) and the FDA's Food Safety Modernization Act (FSMA).

When I am not traveling for work, I work remotely from home in Green Bay, Wisconsin, where I live with my husband and an adorable Bernedoodle. In 2019 my two sons both made me Nana.

Experience

Kathy Knutson Food Safety Consulting LLC
7 years 8 months

Guest Speaker, Advisory Board Member
March 2022 - Present (1 year 6 months)
Globally

<<Bates Number MMAD#6#1>>

I am available for work as a guest speaker for any level within an organization from line workers to investors. I am available to serve as an external technical resource such as serving on an advisory board. I have been working full-time for over six years as a consultant for the delivery of webinars, creation of documents remotely, and boots-on-the-ground support for food and cannabis-infused edibles manufacturing. I have built a wealth of experience through observation, trouble-shooting, and developing programs to meet FDA compliance.

Lead Instructor & Preventive Controls Qualified Individual (PCQI)
January 2016 - Present (7 years 8 months)

Nationwide, call 920.309.2412 mobile

As a PCQI myself, I work remotely from home and travel to work on-site as a consultant with facilities in support of action plans to meet the requirements of FSMA or state code. I'm available for project work writing food safety plans with standard operating procedures and forms for documenting them as well as food microbiology, hazard analysis, and Good Manufacturing Practices with subject matter expertise.

I lead a three-day, on-site PCQI training workshop for food company employees as defined and required by FSMA and as recognized by the FDA. I facilitate training sessions and small-group discussions. I received Lead Instructor certification in 2016 from the Food Safety Preventive Controls Alliance with the FDA-recognized curriculum. Individuals completing the workshop receive an endorsed PCQI certificate of participation and recognition. All food companies are now under FDA compliance for the Preventive Controls for Human Food rule.

NSF International

Independent Contractor

June 2016 - Present (7 years 3 months)

Nationwide

I started with NSF as a Lead Instructor for the FDA Preventive Controls for Human Food rule which requires a Preventive Controls Qualified Individual (PCQI). I have trained PCQIs across the nation. In addition to the PCQI training, I deliver webinars on Food Defense and on Food Allergens. I deliver training on Environmental Monitoring on-site, and NSF is looking to offer this training as a webinar. The webinars are interactive with me through the software and have been very well received.

ImEpik www.imepik.com

Project Manager

October 2018 - Present (4 years 11 months)

I work remotely from home.

ImEpik offers an online, self-paced course to meet the FDA requirement for Preventive Controls Qualified Individual (PCQI). I am updating the curriculum to keep the course current with the FDA rule and guidance, and I am writing a new course for cannabis manufacturers.

EAS Consulting Group, LLC

Independent Contractor

April 2018 - Present (5 years 5 months)

Nationwide

As a contracted consultant, I work with the food and cannabis industries on urgent issues on a project basis. I have reviewed documentation and written reports from home. I have traveled to facilities to conduct a risk assessment of the environment and observe Good Manufacturing Practices (GMPs).

Kornacki Microbiology Solutions, Inc.

Consulting Microbiologist

January 2016 - Present (7 years 8 months)

Nationwide

I joined Dr. Jeff Kornacki in his pursuit of the elusive pathogen in food and manufacturing environments. I investigate the root cause of contamination, research topics of interest within food safety, consult with attorneys and food company clients, write technical reports, and other work in support of the food industry.

Jeff and I, along with CloroDiSys, delivered a three-day workshop in March 2017 and then in February 2018, covering current issues in food safety.

The co-sponsored workshop is in Atlanta in February 2019 at the Emory Conference Center. <https://foodsafetycon.com/>

ConnectFood

Expert Services Team Member & Blogger

August 2012 - Present (11 years 1 month)

Chicago, IL

As a member of the Expert Services Team, I work one on one with professionals in the food industry to write and review their plans remotely.

ConnectFood offers an online HACCP and food safety plan builder with

software support for a user-friendly program for creating a flow diagram, hazard analysis, CCPs and preventive controls.

At the ConnectFood website, I post to a food safety blog based on my experience working with industry and as a Lead Instructor for the FDA-recognized curriculum for Preventive Controls Qualified Individuals (PCQI). I monitor industry news and communication from FDA, USDA and CDC for content.

Northland Laboratories

3 years 6 months

Proficiency Program Coordinator

January 2016 - August 2016 (8 months)

Green Bay, Wisconsin Area

Food Safety Educator

March 2013 - August 2016 (3 years 6 months)

Northbrook, IL; Green Bay, WI

I delivered workshops to members of the food industry, including lab techs, QA managers, sales, purchasing, production managers, sanitation and product development scientists.

Notre Dame de la Baie Academy

Chemistry Teacher

August 2014 - May 2015 (10 months)

Green Bay, Wisconsin Area

I taught five sections of high school chemistry to juniors.

Cherney Microbiological Services

Project Manager

January 2014 - July 2014 (7 months)

Green Bay, Wisconsin

I managed non-routine testing and project work, evaluated lab instruments and methods and wrote technical reports for clients.

The Traveling Vineyard

Wine Marketing Consultant

May 2012 - December 2013 (1 year 8 months)

Illinois

I hosted in-home wine tasting experiences for wine enthusiasts and their guests.

Homewood-Flossmoor High School

Culinary Arts Teacher

2008 - 2011 (3 years)

Flossmoor, IL

I taught Culinary Arts with Family and Consumer Science certification.

Chicago High School for Agricultural Sciences

Food Science Teacher

2005 - 2008 (3 years)

Chicago, IL

I taught Food Science to sophomores, juniors and seniors, where all 600 students were members of the National Future Farmers of America (FFA). I also volunteered as advisor to the sophomore class student organization and coached the dairy product judging team of the National FFA organization at the FFA Dairy Foods Career Development Event (CDE).

Silliker

Technical Director-Microbiology & Education Consultant

February 1999 - July 2004 (5 years 6 months)

Chicago Heights, Illinois

I served as the in-house technical resource for staff and clients. As part of the management team, I supervised the media prep team and one quality technician. I was responsible for customer service and assisted with environmental monitoring with clients to determine testing and interpret results. Trained on PCR. When I left, the lab was converting to LIMS. Later in 2003-2004 I returned to create training materials and deliver external workshops.

IIT, Institute of Food Safety & Health, formerly National Center for Food Safety & Technology

Outreach Manager, Director of Graduate Studies, and Adjunct Professor

January 2000 - May 2003 (3 years 5 months)

Summit, Illinois

Outreach Manager: As part of the management team, I arranged meetings, workshops, and task forces to bring together professionals from industry, government and academia. On a daily basis, I worked with IIT professors and FDA research scientists on food safety issues with Listeria, E. coli O157:H7, sprouts, high pressure processing, ultrapasteurization of dairy fluids, botulinum toxin and mycotoxin. I supervised the technical editor of the newsletter, two administrative assistants and a graphic designer.

Exhibits Number MMAD#6#1>>

I served as event management for an international conference with break-out sessions during the height of concern with acrylamide in processed foods. I created Juice HACCP training materials in cooperation with FDA, industry and academia and arranged and staffed train-the-trainer Juice HACCP workshops across the US. Other responsibilities included designing materials and staffing the expo booth at conferences.

Director of Graduate Studies: I managed the master's degree programs housed in the Summit-Argo campus of IIT and taught Food Microbiology as part of master's degree programs for IIT. I reviewed graduate student applications and research laboratory assignments.

Adjunct Professor: I taught graduate-level Food Microbiology.

Northeast Wisconsin Technical College
Instructor, Food and Environmental Laboratory Technician Program
August 1992 - January 1999 (6 years 6 months)
Green Bay, Wisconsin Area

I taught a wide range of courses: Laboratory, Principles, Standards and Practices; Laboratory Math and Statistics; Laboratory Quality Assurance/Quality Control; Food Science; Environmental Science; Sensory Methods; General Microbiology; Food Microbiology; Analytical Chemistry; and Internship.

I worked with local food and environmental labs to meet industry needs in education of lab techs and place graduates in jobs. I ordered supplies, equipment and educational materials.

I served as an active member of professional organizations related to food, environmental and laboratory operations and attended training workshops and conferences to keep current, and was the advisor of the Food and Environmental Laboratory Technician Club.

Roth Kase AG and USA
Dairy Microbiologist
July 1991 - August 1992 (1 year 2 months)
Monroe, WI

I acquired Gruyere cheese smear cultures from the factories in Switzerland and the growth of the same cultures in Monroe for use on the first Gruyere production in the United States.

Jefferson Center Dairy
Dairy Microbiologist
January 1991 - June 1991 (6 months)
Juda, WI

Start-up and repair of cheese factory.

AuroTech Inc.
Dairy Microbiologist
March 1990 - September 1990 (7 months)
Menomonee Falls, WI

While writing my dissertation and as part of the management team for a dairy-based flavor manufacturer, I conducted research on yogurt cultures.

Merkts Cheese Company
Quality Control Technician
August 1983 - June 1984 (11 months)
Bristol, WI

I performed standard methods for Babcock fat, moisture, acidity, salt, Aerobic Plate Count, Yeast and Mold Count, and Coliform Count.

Note: Merkts Cheese Company is now part of Bel Brands USA.

Education

University of Minnesota
Doctor of Philosophy (Ph.D.), Food Science · (1987 - 1991)

Eastern Illinois University
Teaching Certificate, Family and Consumer Science - Foods · (2009 - 2010)

University of Wisconsin-Madison
Master of Science (M.S.), Food Science · (1985 - 1986)

University of Wisconsin-Madison
Bachelor of Science (BS), Bacteriology · (1979 - 1983)

United States Food and Drug Administration
Consumer Complaint / Injury Report

Exhibit 10

This is an accurate reproduction of the original electronic record as of 03/01/2023

COMPLAINT # 170623

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/14/2021	SEA-DO	CHI-DO	Telephone	Consumer	Muir, Sunny R	In Progress - Pending Evaluation

Complainant Identification

Name	Address	Phone (W)	Phone (H)	Source POC Name	Source Phone
(b) (6)	(b) (6)	UKN	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
<p>On 10/14/21, a complainant called and alleged her husband had a cough and sore throat after consuming (b) (4) Cheese Flavored Snacks packaged in a 20 oz, 1.4 oz rigid plastic container with screw on lid with a heat sealed film. She stated that in addition to her husband, she consumed the product, as well as, her mother and daughter however, none of these individuals got sick. She indicated her husband did not seek medical attention because he was unsure if the symptoms were due to seasonal allergies or eating the product. The complainant stated she purchased the product from the (b) (4) on 10/13/21. On 10/13/21, she attempted to unscrew the lid, but was not able to. Her husband unscrewed the lid and the complainant stated the plastic film looked as though it had been burnt around the edges and was discolored. The complainant stated the lid also appeared to have a burn mark where the plastic film can into contact with the lid. The four individuals that ate the product stated it tasted like "plastic" The complainant called and reported the complaint to (b) (4) Customer Service.</p>	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	10/17/21	Other - identify in Remarks

On 10/19/21, I spoke to (b) (6), (b) (4) Team Supervisor, (b) (4) who told me she was not aware of any similar complaints regarding the product, but would reach out to the manufacturer who is a co-packer for (b) (4). (b) (6) indicated it was probably due to the heat seal being burnt. (b) (6) contacted me after speaking to the manufacturer, Creative Werks in Bartlett, IL, who told her they had not received any similar complaints and were not aware of any issues.

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	10/19/2021	No	No	No	Reported to Manufacture	r

Date: 03/01/2023

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Complaint # 170623

Remarks

Sore throat cough

Complaint Symptoms

Symptom	System Affected	Onset Time	Duration	Remarks
Coughing	RESPIRATORY	Hours	Hours	
Sore throat	RESPIRATORY	Hours	Hours	

Health Care Professional

Provider Name	Address	Phone	Occupation
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Hospital Information

Hospital Name	Address	Phone	Dates of Stay
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Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
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Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
(b) (4)	(b) (4) Cheese Flavored Snacks	07BHT03	Cheese Puffs, Fired;Nonflex Plastic;Packaged Food (Not Commercially Sterile)	03R801	02840056427

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
21.4 Ounces Jar	(b) (4)	22 FEB 2022	10/13/21	No	10

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
10/13/21	10/13/21	REMAINING CONTAINER	No	United States	Primary panel has red, orange, yellow, and black print, packaged in a plastic container screw top lid with plastic heat sealed film

Retail

Name	Address
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(b) (4)

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)	(b) (4)	DAL-DO	Corporate Headquarters
3011417063	Creative Werks 1350 Munger Rd Bartlett Illinois United States 60103-1698	CHI-DO	Manufacturer

Problem Ingredient Group

Date: 03/01/2023

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Complaint # 170623

Initial Evaluation/Initial Disposition

Problem Keyword

Off-Taste

Problem Keyword Details

burnt plastic taste

Initial Evaluation

Initial Disposition

Disposition Made By

Disposition Date

Initial Disposition Remarks

Manufacuter identified by (b) (6), (b) (4) Team Supervisor, (b) (4).

Referrals

Org Name

CHI-IB

HHS Mail Code

HFR-MW150

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Related Complaints

United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 03/01/2023

COMPLAINT # 177322

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
10/20/2022	BLT-DO	CHI-DO	Telephone	Consumer	Johnson, Jacqueline	In Progress - Pending Evaluation

Complainant Identification

Name Address

(b) (6)

Phone (W) Phone (H) Source POC Name Source Phone

(b) (6)

Complaint/Injury

Complaint Description

The complainant reported on October 18, 2022 she purchased one box of (b) (4) from (b) (4) SuperMarket. Upon arrival to her home she placed the unopened box of cereal on the top of her refrigerator. On October 19th the complainant, her (b) (6) daughter and her (b) (6) consumed the (b) (4) cereal. The complainant stated that she consumed on bowl with milk, and then later dry cereal placed inside a ziploc bag. The complainant's daughter consumed on bowl of the cereal with (b) (4) Milk and her son consumed two large bowls with 2% Milk. The complainant stated that within 1/2 hours she began to experience abdominal pains and gas; and within one hour she developed nausea, vomiting and diarrhea which lasted for 24 hours. She reported that her son and daughter both became ill with diarrhea as well. The complainant reported that no one in the family suffers with allergies. They did not seek medical attention. A 72 hour food history was requested from the family members who consumed the product.

Adverse Event Result

Non-Life Threatening Injury/Illness - No Adverse Event Reporting

Adverse Event Date

October 19, 2022

Injury / Illness

Gastrointestinal distress

Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	10/21/2022	No	No	No	Not Reported to Manufacturer	Unknown

Remarks

10/21/2022 additional information requested. CC form and 72 hour food history was requested from all members of the family who consumed the product.

Milk:

(b) (4) 2% purchased on October 8, 2022 via Amazon Fresh Net Wt. 1 Gallon Lot# (b) (4) Expiration Oct 25, 2022 Bar Code: (b) (4) Distributed by: Amazon.com LLC (b) (4) Lactate 2% Reduced Fat Milk purchased on October 18, 2022 (b) (4) SuperMarket 1/2 Gallon Lot# (b) (4) Expiration Date Dec 2, 2022 Barcode (b) (4) Distribute by: (b) (4)

10/27/2022 spoke with general mills representative who will call back/or email with mfg plant information and case #. 11/2/2022 received email from (b) (6), Information Specialist, (b) (4)

Date: 03/01/2023

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<<Bates Number MMAD#6#1>>

Complaint # 177322**Manufacturer/Distributor**

FEI	Name & Address	Home District	Firm Type
3011417063	Creative Werks 1350 Munger Rd Bartlett Illinois United States 60103-1698	CHI-DO	Manufacturer

Initial Evaluation/Initial Disposition**Problem Keyword**

Allergic Reaction

Problem Keyword Details

Vomitting, Diarrhea, Headache Abdominal pain

Initial Evaluation**Initial Disposition****Disposition Made By****Disposition Date****Initial Disposition Remarks**

11/2/2022 received manufacturer information from (b) (6), Information Specialist, (b) (4)
(b) (4)

Referrals**Org Name****HHS Mail Code**

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

Related Complaints

Complaint # 177322

(b) (4); she provided the manufacturer information

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Vomiting	GASTROINTESTINAL	1 Hours	24 Hours	developed nausea and vomitting within one hour and lasting approximately 24 hours
Diarrhea	GASTROINTESTINAL	1 Hours	24 Hours	developed diarrhea one hour lasting 24 hours
Abdominal cramps	GASTROINTESTINAL	Immediate	24 Hours	Gas and stomach pain thirty minutes after consuming milk and cereal

Health Care Professional

Provider Name	Address	Phone	Occupation
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Hospital Information

Hospital Name	Address	Phone	Dates of Stay
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Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
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Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
(b) (4)	(b) (4)	05YFE99	Cereal Preparations Not Elsewhere Mentioned, N.E.C.;Paper;Commercially Sterile	03R801	0160001564 32

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
32 Ounces Box	(b) (4)	09/02/2023	October18, 2022	Yes	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No	United States	

Retail

Name	Address
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(b) (4) SuperMarket	(b) (4)
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Problem Ingredient Group

Date: 03/01/2023

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<<Bates Number MMAD#6#1>>

Complaint #177322

COMPLAINTS FOLLOW - UP**Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
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There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code
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